

A PHARMACEUTICAL COMPOSITION FOR TREATING RHEUMATISM AND THE PREPARATION THEREOF

CROSS-REFERENCE TO RELATED APPLICATION

This application is a National Phase Patent Application and claims the priority of International Application Number PCT/CN2002/00246, filed on April 9, 2002.

THE FIELD OF THE INVENTION

The invention is ~~about~~directed to a medicine ~~which is used to treat~~for treating rheumatism, and ~~its~~the medicine's preparation.

THE BACKGROUND OF THE INVENTION

It is believed that ~~the~~ rheumatoid arthritis (RA) is refractory and about 18,000,000 RA patients have been disabled because of this disease. The ~~medicine research~~for medical research into curing RA has continued for about a century. Aspirin is the first medicine which ~~is~~was widely used to treat RA. The medicine to treat RA can be divided into 2 kinds: non-steroidal anti-inflammatory drugs (NSAIDs) and immunosuppressive ~~agent~~agents. NSAIDs includes cyclophthasine, antinfan and adrenal cortex hormone. ~~The clinical researchs have proved~~Clinical research has proven the effectiveness of NSAIDs. ~~The immunosuppressive agent includes~~Immunosuppressive agents include methotrexate, cyclophosphane, penicillamine and ~~et al.~~ ~~The immunoregulation~~among others. Immunoregulation has become one of the important ~~therapi~~estherapies in ~~the~~ recent years. But all the medicines ~~which are~~ used to treat rheumatism have serious side-

1 ~~effect~~effects. The ~~A~~ medicine ~~which~~that can treat rheumatism effectively
2 and ~~non-poisonously~~ hasn't nontoxically has not been invented by
3 ~~now~~before the present invention.

4 There are 3 directions in the research of
5 ~~antirheumatic~~antirheumatics that should be emphasized. The first
6 direction is NSAIDs and cytokine-~~antagon~~antagonists, such as
7 ~~recombined~~recombinant, soluble TNF~~antagon~~TNF α antagonists, IL-1
8 ~~inhibitor~~inhibitors and PAF ~~inhibitor~~(platelet-activating factor)
9 inhibitors. The second direction is the new immunosuppressive
10 ~~agent~~agents and ~~immunomodulator~~immunomodulators, such as
11 cyclosporin A. The third direction is the compound medicines.

12 In the ~~TCM~~traditional Chinese medicine (TCM), the research on
13 ~~the "arthralgia disease"~~(equals "Bi Zheng" (equivalent to the definition
14 of rheumatism or arthralgia in the modern medicine) can be traced back
15 to the Han dynasty more than 1,500 years ago. Three prescriptions: "Ma
16 Xing Shi Gan decoction", "Fangji ~~Huangqi~~Huangqi decoction" and
17 "~~Wutong~~Wutou decoction", ~~which is~~ were used to treat "Bi Zheng"
18 ~~were~~as recorded in the ~~medicine~~medical classics "Shanghan Lun"
19 ~~wrote~~written by the famous doctor Zhang Zhongjing at that time. A
20 wild plant called "huo ba hua" (Gelsemium ~~elegan~~selegans Benth ~~is a~~
21 ~~kind of wild plant in Sichuan~~ in Sichuan province ~~and it has been~~
22 ~~proved~~proven effective ~~to treat~~ in the treatment of rheumatism ~~in a~~
23 on clinical research ~~carried at~~ performed in the local area. ~~But the further~~
24 (Sichuan province). However, subsequent study found that it had a
25 serious side-effect on the ~~reproduction~~reproductive organs and ~~some~~
26 other uncontrollable ~~problem~~problems.

1 The treatment of “~~arthralgia—disease~~Bi Zheng” by the
2 ~~method~~methods of TCM has reached a high level after a long history of
3 development by numerous doctors’ ~~development in so long a history. By~~
4 ~~now.~~ Currently, there are many effective prescriptions and herbs. There
5 ~~are more~~More than 80 kinds of herbs and 29 kinds of patent medicines
6 are recorded in the China pharmacopoeia 1995 edition and 2000 edition.
7 ~~But there are still~~However, many problems still remain; for example:, ①
8 ~~the effect is not good enough~~ TCM is still ineffectual in treating the
9 serious arthralgia—disease such as rheumatoid arthritis; ② the dosage
10 forms ~~are not fit for~~cannot meet the needs of modern life. ③ some
11 medicine ~~has~~have good ~~effect~~effects, but the side-effect is ~~serious~~effects
12 are too damaging, such as when using the extract of *triperygium*
13 *wilfordii*. ~~So that~~Thus, it is necessary to develop ~~the~~a new antirheumatic
14 medicine that is highly-effective-lowly-noxious, with minimal
15 noxiousness, and convenient for ~~administration—~~antirheumatic
16 ~~medicine to administer.~~ This medicine should have ~~the—~~similar
17 ~~effect~~effects and ~~the lower side effect to the~~effects than artificial
18 ~~antirheumatic,~~ anti-rheumatic medicine.

19 20 THE CONTENT SUMMARY OF THE INVENTION

21 The invention ~~is to supply~~provides an antirheumatic, ~~which that~~ is
22 highly-effective-lowly-noxious, has minimal noxiousness, and is
23 convenient ~~for administration~~to administer, and its preparation thereof.

24 The ~~invented medicine’s technical proposal is realized by using~~
25 ~~the~~medicine uses the following crude herbs ~~as following~~:

26 *Tripterygium hypoglaucum* (Levl.) Hutch;

Epimedium brevicornum Maxim.;

Lycium barbarum L.; and

Cuscuta chinensis Lam. (or *Cuscuta australis* R. Br.)

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

The ~~invented medicine is made from the crude herbs~~
~~above.~~ antirheumatic medicine of the present invention utilizes the crude
herbs as follows:

Tripterygium hypoglaucum (Levl.) Hutch;

Epimedium brevicornum Maxim;

Lycium barbarum L.; and

Cuscuta chinensis Lam (or *Cuscuta australis* R. Br.)

The ~~material~~ crude herbs to produce the ~~invented~~ antirheumatic
medicine can be combined ~~on~~ in several ways. The *tripterygium*
hypoglaucum (Levl.) Hutch. is the necessary herb, with one or two or
three of the other three herbs ~~can be added to make~~ to make the
~~material~~ medicine.

One of the optimal proportional combinations of crude herbs ~~rate~~
~~off~~ for the material medicine is as ~~following~~ follows:

Tripterygium hypoglaucum (Levl.) Hutch. 1-4

~~weight in weight~~ parts by weight

Epimedium brevicornum Maxim. 1-4

~~weight in weight~~ parts by weight

Lycium barbarum L. 1-4

~~weight in weight~~ parts by weight

Cuscuta chinensis Lam. 1-4 ~~weight in weight~~

parts by weight

~~The other~~ A second optimal proportional combination of crude herbs rate ~~offor~~ the materialmedicine is as following follows:

Tripterygium hypoglaucum (Levl.) Hutch. ——— 2 ~~weightinweight~~
2 parts by weight

Epimedium brevicornum Maxim. ——— 2 ~~weightinweight~~

Lycium barbarum L. ——— 1 ~~weightinweight~~

Cuscuta chinensis Lam. ——— 1 ~~weightinweight~~

Epimedium brevicornum Maxim. 2 parts by weight

Lycium barbarum L. 1 parts by weight

Cuscuta chinensis Lam. 1 parts by weight

The third optimal proportional combination of crude herbs rate ~~offor~~ the materialmedicine is as following follows:

Tripterygium hypoglaucum (Levl.) Hutch. 1-4
~~weightinweight~~ parts by weight

Epimedium brevicornum Maxim. 1-4
~~weightinweight~~ parts by weight

The fourth optimal proportional combination of crude herbs rate ~~offor~~ the materialmedicine is as following follows:

Tripterygium hypoglaucum (Levl.) Hutch. 2
~~weightinweight~~ parts by weight

Epimedium brevicornum Maxim. 2
~~weightinweight~~ parts by weight

The fifth optimal proportional combination of crude herbs rate ~~offor~~ the materialmedicine is as following follows:

Tripterygium hypoglaucum (Levl.) Hutch. 1-4
~~weightinweight~~ parts by weight

Epimedium brevicornum Maxim 1-4

~~weightinweightparts by weight~~

Lycium barbarum L 1-4

~~weightinweightparts by weight~~

The sixth optimal proportional combination of crude herbs ~~rate~~
~~effor~~ the ~~material~~medicine is as ~~following~~follows:

Tripterygium hypoglaucum (Levl.) Hutch 2

~~weightinweightparts by weight~~

Epimedium brevicornum Maxim 2

~~weightinweightparts by weight~~

Lycium barbarum L 1

~~weightinweightparts by weight~~

The seventh optimal proportional combination of crude herbs ~~rate~~
~~effor~~ the ~~material~~medicine is as ~~following~~follows:

Tripterygium hypoglaucum (Levl.) Hutch 1-4~~weightinweight~~
~~parts by weight~~

Epimedium brevicornum Maxim 1-4

~~weightinweightparts by weight~~

Cuscuta chinensis Lam 1-4

~~weightinweightparts by weight~~

The eighth optimal proportional combination of crude herbs ~~rate~~
~~effor~~ the ~~material~~medicine is as ~~following~~follows:

Tripterygium hypoglaucum (Levl.) Hutch 2

~~weightinweightparts by weight~~

Epimedium brevicornum Maxim 2~~weightinweight~~

~~parts by weight~~

Cuscuta chinensis Lam 1

~~weightinweightparts by weight~~

The content of the ~~icariine~~icariin ($C_{33}H_{40}O_{15}$) in the medicine combinations above ~~can~~should not be less than 2.0 mg.

The optimal proportional combinations of crude herbs ~~rate of~~for the ~~material~~medicine can be ~~the~~derived in other ~~way~~ways as ~~following~~follows:

Tripterygium hypoglaucum (Levl.) Hutch 1-4

~~weight in weight~~parts by weight

Lycium barbarum L 1-4

~~weight in weight~~parts by weight

And / or *Cuscuta chinensis* Lam 1-4

~~weight in weight~~1-4 parts by weight

~~The optimal crude herbs rate of the material can be another way as following:~~

The optimal proportional combinations of crude herbs for the medicine can be derived in another way as follows:

Tripterygium hypoglaucum (Levl.) Hutch—2—~~weight in weight~~2 parts by weight

Lycium barbarum L—1—~~weight in weight~~

Lycium barbarum L 1 part by weight

And / or *Cuscuta chinensis* Lam 1

~~weight in weight~~part by weight

The crude herbs are prepared ~~on the rate~~based on their proportional combinations and then they can be made into any dosage forms used in the clinic, such as the bolus form, the powder forms, the ointment forms, the tablet forms, the ~~soft~~soft or hard capsule forms, the granule forms, the injection forms and so on.

The preparation method of the invented medicine is as

following follows:

The crude herbs are prepared based on the proportional weight-rate:

Tripterygium hypoglaucum (Levl.) Hutch 1-4

~~weightinweight~~ parts by weight

Epimedium brevicornum Maxim 1-4

~~weightinweight~~ parts by weight

Lycium barbarum L 1-4

~~weightinweight~~ parts by weight

Cuscuta chinensis Lam 1-4

~~weightinweight~~ parts by weight

The *Tripterygium hypoglaucum* (Levl.) Hutch. and *Epimedium*

brevicornum Maxim are ~~smashed~~ broken into pieces. Then the

~~powders~~ pieces are decocted by water for 2 ~ 4 times separately. The

Lycium barbarum L and *Cuscuta chinensis* Lam are soaked in the hot

water (80~95°C) for 1 ~ 3 times separately. The ~~decocted~~ decoction fluid

and the immersion fluid of the herbs are collected and added separately

to the ~~correspondent~~ macroscopic void ~~corresponding~~ column of

adsorbent resins ~~column separately~~ having macroscopic voids. After the

adsorption, the columns are washed with water until the flushing liquor

~~turns~~ liquid turns clear. Then the ~~columns~~ resins are eluted ~~by~~ with 60%-

80% alcohol. The ~~eluting liquor~~ eluted liquids are collected from ~~its~~ the

time when their color ~~turning~~ turns deep ~~till the~~ until their color

~~turning~~ turns very weak. Then the remaining alcohol in the ~~upper part of~~

~~the~~ column is pushed out by high pressure water and ~~mixed with the~~

~~eluting liquor~~. The ~~mixed eluting liquor~~ is 3 ~ 8 times heavy of the

~~correspondent~~ is added to the eluted liquids. The combined eluted liquids

are about 3 ~ 8 times more concentrated than the corresponding crude herb in terms of the effective compounds. All the 4 eluting liquors 4 eluted liquids are recycled and condensed to the a specific density 1.10 separately of 1.10. The condensed liquors are dehydrated dried by spray spray drying method to get the extract of the crude herbs. The 4 kinds kinds of extracts are mixed uniformly to be made into any appropriate dosage forms that are needed by the clinic.

The optimal preparation method of the invented medicine is as following follows:

The crude herbs are prepared based on the proportional weight rate:

Tripterygium hypoglaucum (Levl.) Hutch — 2 weight in weight

Tripterygium hypoglaucum (Levl.) Hutch 2 parts by weight

Epimedium brevicornum Maxim 2
weight in weight parts by weight

Lycium barbarum L 1
weight in weight part by weight

Cuscuta chinensis Lam 1
weight in weight part by weight

The *Tripterygium hypoglaucum* (Levl.) Hutch. Is smashed is broken into pieces. Then the powder is pieces are added with 13, 10, 10 fold volume weight of the water to decoct for 3 times respectively. Each time is for 1 hour. The *Epimedium brevicornum* Maxim is cut to piece into pieces. Then the herb pieces is are added with 15, 10, 10 fold volume weight of the water to decoct for 3 times respectively. Each time is for 1 hour. The *Lycium barbarum* L is smashed to crude broken

1 into coarse powder and soaked in ~~the~~ hot water (80°C, 20 ~~fold~~volume
2 weight of the crude herb) ~~for~~ 3 times. Each time is for 1 hour. The
3 *Cuscuta chinensis* Lam is ~~smashed~~broken to ~~crude~~coarse powder and
4 soaked in the hot water (80°C, 31 ~~fold~~volume weight of the crude herb)
5 ~~for~~ 3 times. Each time is for 1 hour. The ~~decocted~~decoction fluid and the
6 immersion fluid of the herbs are filtrated separately and added to the
7 ~~correspondent macroscopic void~~corresponding column of adsorbent
8 resins ~~column~~having macroscopic voids (the type of the resin is JD-1
9 (WLD resin)). After ~~the~~ adsorption, the resins in the columns are eluted
10 by 70% alcohol. The ~~eluting liquors~~eluted liquids are collected from
11 ~~its~~when the color ~~turning of the liquid turns~~ deep ~~till~~until the color
12 ~~turning of the liquid turns~~ very weak. The alcohol is ~~reecycled~~separated
13 from the ~~eluting liquor~~eluted liquid. Then the ~~rest liquor~~remaining
14 eluted liquid is condensed and ~~dehydrated to get~~dried to obtain the
15 extract powder. The 4 ~~kind~~kinds of extract powders are mixed uniformly
16 to be made into any dosage forms that are needed by the clinic.

17 The invented medicine can be prepared ~~on~~by the method as
18 following follows:

19 The crude herbs are prepared based on the proportional weight rate
20 ~~recorded before~~described above. The *Tripterygium hypoglaucum* (Levl.)
21 Hutch. and *Epimedium brevicornum* Maxim are cut into pieces. The
22 *Lycium barbarum* L and *Cuscuta chinensis* Lam are crushed or not
23 crushed. The 4 ~~kind~~kinds of herbs are extracted ~~in the using~~ 0~95%
24 alcohol at 10 ~ 98°C for 1~4 times separately or together. The extracted
25 ~~liquors~~liquids are mixed or not mixed. Then the extracted ~~liquors~~liquids
26 are condensed, ~~dehydrated, smashed~~dried, broken into pieces and mixed

1 uniformly. The mixed powder can be made into any dosage form needed
2 in the clinic.

3 The invented medicine can be made from the effective constituents
4 of the 4 herbs.

5 The effective constituents of *Epimedium brevicornum* Maxim are
6 ~~icariine~~icariin, icaraside I , icaraside II, and Icariin A. The effective
7 constituents of *Tripterygium hypoglaucum* (Levl.) Hutch. ~~Are~~are
8 diterpenes, triterpenes and alkaloids ~~compound~~compounds. The effective
9 constituents of *Lycium barbarum* L and *Cuscuta chinensis* Lam are both
10 ~~flavone~~flavones.

11 ~~So that the~~The crude herb *Epimedium brevicornum* Maxim can be
12 replaced by one or more kinds of the effective constituents of itself, such
13 as ~~icariine~~icariin, icaraside I , icaraside II, and Icariin A. The crude herb
14 *Tripterygium hypoglaucum* (Levl.) Hutch. ~~Can~~can be replaced by one or
15 more kinds of the effective constituents of itself, such as diterpenes,
16 triterpenes and alkaloids ~~compound~~compounds. While the *Lycium*
17 *barbarum* L and *Cuscuta chinensis* Lam can be replaced by
18 ~~flavone~~flavones.

19 It has been ~~proved~~proven by the pharmacodynamics research that
20 the invented medicine (Fengshiping Capsule) ~~could~~can inhibit the
21 primary and secondary injury adjuvant arthritis (AA). It ~~could~~can inhibit
22 the delayed hypersensitivity (DTH) in the ear of ~~the~~a mouse caused
23 by the 2,4 dinitrofluorobenzene (DNFB). It ~~could~~can inhibit the ~~antibody~~
24 ~~produce of the~~production of hemolysin antibody and the activity of the
25 IL-1, IL-2, IL-6 and TNF in the macrophage and splenocyte. The
26 Fengshiping Capsule ~~could~~can inhibit the lymphocyte transformation

1 induced by the ConA. It ~~could~~can inhibit the CD₄、CD₈ cells
2 remarkably, especially CD₄ cells, but ~~the rate~~it does not affect the
3 relative proportion of CD₄/CD₈ ~~was not affected~~ very much. There was a
4 remarkable linear relationship between the dosage and the effect. Twelve
5 to eighteen (12~18) g (crude medicine)/kg was the minimum effective
6 dose. The invented medicine ~~could~~can inhibit the activity of the NK
7 (Natural Killer) cells. ~~In~~At the effective dose, Fengshiping Capsule did
8 not cause the atrophy of the important immune organs such as thymus
9 and spleen, and did not inhibit the phagocytic activity of the
10 macrophage.

11 The invented medicine had a remarkable ~~antiinflammatory~~anti-
12 inflammatory action. It ~~could~~can inhibit the ~~over~~excessive penetrating
13 ~~condition~~damage of the capillary in the mouse's abdominal cavity
14 caused by the ~~ethanoie~~injection of acetic acid—~~injected~~. It ~~could~~
15 ~~improve~~can inhibit the swelling in the ear of the mouse caused by the
16 croton oil. It ~~could~~can inhibit the pleuritis in the mouse and the
17 assembling of the WBC (white blood cells) to the CMC cyst in the rat
18 induced by the carrageenan. But the invented medicine ~~couldn't~~cannot
19 obviously inhibit the rat's foot swelling induced by the carrageenan and
20 the granuloma caused by the tampon—~~obviously~~. The Fengshipng
21 Capsule ~~could~~can remarkably inhibit the body-twist reaction caused by
22 the ~~ethanoie~~acetic acid in the mouse ~~remarkably~~.

23 Experimental example 1: the effect on the adjuvant arthritis (AA)

24
25 1.1 The ~~preventing~~preventive effect on the AA of the invented
26 medicine

1 Seventy-two (72) isogenous SD rats of the same batch, half male
2 and half female, 180 ~ 220g weight each, were divided randomly into 6
3 groups. Each group ~~has~~had 12 rats. ~~Every Six (6)~~ rats lived in a cage.
4 The perimeter of the double ~~ankle joints~~ankle joints and the feet of the
5 ~~rat~~rats were measured accurately and recorded as the normal value. All
6 the rats were ~~drenched by~~given orally the same volume of the invented
7 medicine ~~on the correspondent concentration or at~~ different
8 concentrations of the solution ~~of the Xihuangqi by the gastric injection~~.
9 with tragacanth. One (1) hour later, all the rats were injected with 0.1ml
10 Freund's complete adjuvant (FCA) under the skin of the left
11 ~~postpedes~~posterior limb. In the next 30 days, all the rats were ~~drenched~~
12 ~~with~~given orally the correspondent medicine once a day ~~on at~~ the same
13 dosage. And ~~in on~~ these days, the ~~rats were measured of the~~ perimeters of
14 the double ~~ankle joints~~ankle joints and the feet of the rats were measured
15 once a day. In this experiment, the swelling degree (Δ cm)~~equaled to~~
16 equals the difference value of the perimeters measured after the FCA
17 injection and before the FCA injection. (See the result in table 1.1 and
18 1.2) At the end of the experiment, the major organs of the rats were
19 ~~weighted~~weighed. (See the table 1.3, 1.4)

Table 1.1 The effect of the Fengshipping on the swelling degree of the left ankle joint and foot after the injection of FCA in the rat AA model ($\bar{X} \pm S$)

Group	Dose (g/kg)	Swelling degree (Δ cm)						
		1d	2d	3d	9d	12d	14d	16d
Control	-	0.69±0.17	0.69±0.12	0.92±0.18	0.84±0.41	1.10±0.30	1.65±0.68	2.10±0.55
Fengshipping	7.5	0.74±0.12	0.66±0.074	0.83±0.13	0.77±0.27	1.11±0.45	1.34±0.53	1.91±0.61
Fengshipping	15	0.80±0.24	0.62±0.13	0.76±0.18	0.49±0.17*	0.73±0.34*	1.00±0.48*	1.38±0.67*
Fengshipping	30	0.75±0.19	0.67±0.19	0.87±0.28	0.63±0.22	0.73±0.34*	0.82±0.43**	1.05±0.53**
Tripterygium hypoglaucom (Levl.) Hutch.	5	0.72±0.11	0.68±0.16	0.91±0.18	0.66±0.23	0.88±0.29	1.03±0.36*	1.37±0.33*
prednisone	0.01	0.64±0.14	0.64±0.16	0.50±0.26	0.46±0.25	0.72±0.46*	0.87±0.46**	1.28±0.69*

Group	Dose (g/kg)	Swelling degree (Δ cm)					
		18d	20d	22d	24d	26d	28d
Control	-	2.18 \pm 0.44	2.05 \pm 0.46	2.00 \pm 0.46	2.04 \pm 0.57	1.92 \pm 0.65	1.83 \pm 0.67
Fengshipping	7.5	1.74 \pm 0.73	1.81 \pm 0.55	1.81 \pm 0.52	1.77 \pm 0.55	1.65 \pm 0.55	1.55 \pm 0.49
Fengshipping	15	1.32 \pm 0.59**	1.28 \pm 0.58**	1.34 \pm 0.61*	1.33 \pm 0.67*	1.20 \pm 0.64*	1.08 \pm 0.58**
Fengshipping	30	0.95 \pm 0.50**	0.87 \pm 0.51**	0.95 \pm 0.54**	0.89 \pm 0.59**	0.90 \pm 0.57**	0.86 \pm 0.51**
Tripterygium hypoglaucom (Levl.) Hutch.	5	1.47 \pm 0.43**	1.50 \pm 0.43**	1.49 \pm 0.43*	1.42 \pm 0.53*	1.40 \pm 0.56*	1.32 \pm 0.57
prednisone	0.01	1.18 \pm 0.7**6	1.03 \pm 0.67**	1.05 \pm 0.69*	0.90 \pm 0.64**	0.86 \pm 0.65**	0.85 \pm 0.59**

Comparing to the control group *P<0.05 , **P<0.01(the signs have the same meaning in the following tables)

1.2 The effect of the Fengshipping on the swelling degree of the left ankle joint after the injection of FCA in the rat AA model ($\bar{X} \pm S$)

Group	Dose (g/kg)	Swelling degree (Δ cm)				
		2d	9d	12d	14d	16d
Control	-	0.14±0.05	0.06±0.10	0.34±0.36	0.80±0.52	1.43±0.67
Fengshipping	7.5	0.18±0.06	0.10±0.14	0.26±0.36	0.82±0.52	1.31±0.64
Fengshipping	15	0.15±0.08	0.02±0.06	0.13±0.10*	0.37±0.31*	0.90±0.56*
Fengshipping	30	0.18±0.09	0.06±0.06	0.16±0.08*	0.29±0.20**	0.49±0.41**
Tripterygium hypoglaucom (Levl.) Hutch.	5	0.16±0.07	0.01±0.07	0.11±0.10	0.44±0.19**	0.87±0.56*
prednisone	0.01	0.20±0.06	0.08±0.08	0.21±0.16	0.44±0.43	0.99±0.63

Group	Dose (g/kg)	Swelling degree (Δ cm)				
		20d	22d	24d	26d	28d
Control	-	1.28±0.57	1.38±0.64	1.35±0.75	1.20±0.78	1.12±0.63
Fengshipping	7.5	1.33±0.71	1.31±0.73	1.27±0.73	1.16±0.73	1.07±0.65
Fengshipping	15	1.74±0.57*	1.92±0.61*	0.95±0.64*	0.88±0.58*	1.83±0.55
Fengshipping	30	0.27±0.30**	0.34±0.31**	0.32±0.33**	0.31±0.32**	0.34±0.32**
Tripterygium hypoglaucom (Levl.) Hutch.	5	0.82±0.65*	0.89±0.70*	0.80±0.67*	0.83±0.68	0.75±0.69
prednisone	0.01	0.82±0.72*	0.79±0.74*	0.75±0.67**	0.68±0.64*	0.71±0.67

1.3 The effect of the Fengshipng on the body weight of the AA rats ($\bar{X} \pm S$)

Group	Dose (g/kg)	Body weight change(g)		
		InitiativeInitial BW	BW at 1 month later	BW change
Control	-	228±34	231±52	3
Fengshipping	7.5	229±34	220±46	-9
Fengshipping	15	223±40	232±34	9
Fengshipping	30	224±37	256±60	32
Tripterygium hypoglaucum (Levl.) Hutch. prednisone	5 0.01	226±45 264±55	230±43 244±31	4 -21

1.4 The effect of the Fengshipping on the organ weight of the immune system in the AA rats (prevention experiment)($\bar{X} \pm S$)

Group	Dose (g/kg)	Organ index [(organ weight/body weight)/100]			
		Liver	Spleen	Thymus	adrenal gland
Control	-	3.92±0.65	0.34±0.10	0.098±0.040	0.027±0.01
Fengshipping	7.5	3.73±0.29	0.31±0.09	0.078±0.038	0.027±0.008
Fengshipping	15	3.48±0.32	0.38±0.10	0.100±0.034	0.023±0.005
Fengshipping	30	3.38±0.28*	0.44±0.12*	0.100±0.032	0.022±0.007
Tripterygium hypoglaucum (Levl.) Hutch. prednisone	5 0.01	3.21±0.30** 3.04±0.20**	0.36±0.05 0.32±0.08	0.052±0.011** 0.050±0.060**	0.026±0.009 0.020±0.004*

1.2 The therapeutic effect on the AA of the invented medicine

Fifty (50) male SD rats were divided into 5 groups at random. The experimental model building—was the same ~~toas~~ the prevention experiment, but the correspondent medicines were ~~drenched~~given orally 13 days after the injection of the FCA. The medicines were ~~drenched~~given once a day for 2 weeks. The degree of swelling—~~degree~~ (Δ cm) was the difference of the perimeters between the value of first administration day and the other days. (~~Se~~See the result in table 1.5, 1.6) The major organs' weight is showed in table 1.7.

1 **1.5 The therapeutic effect of Fengshiping on the swelling-degree of**
2 **Theswelling of the left anklejoint and foot in the AA rats ($\bar{X} \pm S$)**

Group	Dose (g/kg)	Swelling degree (Δ cm)			
		1d	2d	4d	6d
Control	-	1.81 \pm 0.27	1.92 \pm 0.19	2.12 \pm 0.22	2.16 \pm 0.27
Fengshiping	7.5	1.68 \pm 0.50	1.64 \pm 0.54	1.70 \pm 0.57	1.82 \pm 0.61
Fengshiping	15	1.44 \pm 0.41*	1.51 \pm 0.36**	1.65 \pm 0.34**	1.74 \pm 0.31**
Fengshiping	30	1.50 \pm 0.56	1.48 \pm 0.41**	1.51 \pm 0.44**	1.59 \pm 0.51**
prednisone	0.01	1.78 \pm 0.51	1.70 \pm 0.51	1.63 \pm 0.50*	1.58 \pm 0.50**

3

Group	Dose (g/kg)	Swelling degree (Δ cm)			
		8d	10d	12d	14d
Control	-	1.92 \pm 0.32	1.87 \pm 0.34	1.92 \pm 0.39	1.78 \pm 0.44
Fengshiping	7.5	1.67 \pm 0.68	1.60 \pm 0.71	1.61 \pm 0.77	1.58 \pm 0.71
Fengshiping	15	1.46 \pm 0.37**	1.48 \pm 0.30*	1.28 \pm 0.37**	1.22 \pm 0.38**
Fengshiping	30	1.29 \pm 0.58**	1.29 \pm 0.65**	1.26 \pm 0.67**	1.20 \pm 0.68*
prednisone	0.01	1.27 \pm 0.46**	1.09 \pm 0.54**	0.94 \pm 0.50**	0.94 \pm 0.42**

4

5

6 **1.6 The therapeutic effect of Fengshiping on the swelling-degree of**
7 **swelling of the right anklejoint and foot in the AA rats ($\bar{X} \pm S$)**

Group	Dose (g/kg)	Swelling degree (Δ cm)			
		2d	4d	6d	8d
Control	-	0.36 \pm 0.26	0.45 \pm 0.25	0.55 \pm 0.34	0.47 \pm 0.29
Fengshiping	7.5	0.12 \pm 0.25	0.34 \pm 0.32	0.48 \pm 0.41	0.28 \pm 0.38
Fengshiping	15	0.21 \pm 0.18	0.38 \pm 0.27	0.44 \pm 0.33	0.21 \pm 0.33*
Fengshiping	30	0.10 \pm 0.48	0.06 \pm 0.28**	0.11 \pm 0.24**	0.06 \pm 0.27**
prednisone	0.01	0.10 \pm 0.13*	0.15 \pm 0.28*	0.11 \pm 0.25**	-0.08 \pm 0.34**

Group	Dose (g/kg)	Swelling degree(Δ cm)		
		10d	12d	14d
Control	-	0.48 \pm 0.25	0.46 \pm 0.31	0.40 \pm 0.36
Fengshiping	7.5	0.35 \pm 0.30	0.30 \pm 0.29	0.30 \pm 0.35
Fengshiping	15	0.19 \pm 0.45*	0.06 \pm 0.31**	-0.06 \pm 0.34**
Fengshiping	30	0.02 \pm 0.39**	0.05 \pm 0.38*	-0.02 \pm 0.41**
prednisone	0.01	-0.13 \pm 0.28**	-0.26 \pm 0.36**	-0.33 \pm 0.39**

8 n = 10 , comparing with the control group , *P<0.05 , **P<0.01

9

1.7 The effect of the Fengshiping on the organ weight of the immune system in the AA rats ($\bar{X} \pm S$)

Group	Dose (g/kg)	Organ index [(organ weight/body weight)/100]			
		Liver	Spleen	Thymus	adrenal gland
Control	-	0.35±0.23	0.35±0.061	0.073±0.014	0.026±0.0071
Fengshiping	7.5	3.21±0.52	0.33±0.091	0.071±0.026	0.024±0.0085
Fengshiping	15	3.40±0.54	0.36±0.014	0.067±0.022	0.023±0.0048
Fengshiping	30	2.79±0.43	0.32±0.083	0.069±0.029	0.023±0.0072
Tripterygium hypoglaucomum (Levl.) Hutch.	5	3.92±0.59	0.35±0.100	0.075±0.034	0.027±0.0060
prednisone	0.01	3.52±0.35	0.28±0.047*	0.05±0.011**	0.02±0.0043*

The data ~~showed~~shown in the ~~table~~tables 1.1, 1.2, 1.3, 1.5 and 1.6 ~~proved~~prove that the Fengshiping ~~could~~can strongly inhibit the primary and secondary injury caused by FCA, whenever the medicine was ~~drenched~~given at the beginning of the FCA injection or 2 weeks after the FCA injection. The experiments ~~proved~~prove that the Fengshiping ~~had~~has both the ~~preventing~~preventive and the therapeutic effect. By comparing the effect of Fengshiping on the degree of swelling ~~degree~~ ~~in~~of the anklejoint and foot, we found that the Fengshiping ~~could~~can inhibit the specific ~~immuno~~swelling in the anklejointimmuno-swelling ~~of the ankle joint~~ better than the nonspecific ~~immuno~~swellingimmuno-swelling in the foot of rats. This result ~~indicated~~indicates that the main effect of Fengshiping was inhibiting the ~~immunity~~inflammatory reaction of the immune system.

The data in the ~~table~~tables 1.3, 1.4 and 1.7 ~~showed~~show that the AA rats had no obvious BW (body weight) increase during the period of the experiment. In the group ~~drenched~~of given the Fengshiping ~~on~~with the effective dosage, the rats ~~still had~~BW continued to increase in BW. In the groups ~~of treated with~~ prednisone ~~and preventing~~, the BW of rats ~~had~~ decreased, while the thymus and adrenal gland ~~were~~ atrophied. In the

group ~~of~~ treated with tripterygium hypoglaucum (Levl.) Hutch, the thymus had ~~thinned yet. But in~~ not atrophied. In the 3 groups ~~drenched with~~ given the different dosage of Fengshiping, ~~on~~ no atrophy of the thymus and adrenal gland were observed.

1.3 The pathologic change of the AA after the treatment of the invented medicine in rats

Forty-five (45) SD rats, 180 ± 20 g weight each, were divided into 6 groups. After the AA caused by FCA appeared, all the rats were ~~drenched with~~ given orally, Fengshiping solution ~~by gastic injection~~ for 5 days once a day. One (1) hour after the last administration, the joint index of the rats was measured and calculated. The ~~secondary injured postpedes' damaged joints on~~ of the opposite of posterior limbs distal from the FCA ~~injection~~ injection were ~~taken off~~ removed and soaked in the formaldehyde. After the tissues were ~~HE tinted~~ stained with HE (hematoxylin-eosin), the pathological change of the synovium and cartilage were observed and recorded. The data ~~were showed~~ are shown in table 1.8.

1.8 The effect of Fengshiping on the AA joint index in

the rats ($\bar{X} \pm S$)

Group	Dose (g/kg)	Rat number	Joint index
Control	-	8	0**
AA model	-	7	6.2 ± 0.49
Fengshiping	7.5	9	$4.86 \pm 0.90^{**}$
Fengshiping	15	7	$4.71 \pm 0.95^{**}$
Fengshiping	30	7	$4.56 \pm 1.13^{**}$
Glucosidorum Tripterygll Totorum	0.006	7	$4.57 \pm 0.79^{**}$

Comparing with the model group $^{**}P < 0.01$

1 The joint index was the sum of the inflammatory scores of the four
2 limbs. According to the degree of inflammatory, each limb was
3 evaluated on the criteria as following: normal (0), red without swelling
4 (1), red and swelling (2), seriously swelling (3), ~~deforming~~deformity and
5 ~~tetanus~~stiffness (4).

6 Observed from the microscope, the joint synovial membranes of the
7 rat posterior limb were ~~hyperplasia~~hyperplastic in the ~~model~~control
8 group; ~~and~~ the collagen fiber had increased; and there was infiltration of
9 lymphocytes and plasma cells in the tissue. ~~The~~An obvious granuloma
10 had formed. The synovial cells had degenerated and the cytochylema
11 ~~had been~~was tinted red; the ~~early~~on~~nucleus~~ had ~~been~~pycnosis~~become~~
12 pycnotic; the epithelium had exfoliated in some part of the synovial
13 membrane. The cartilage ~~turned~~atrophy; ~~the~~became atrophied; its
14 surface ~~of it~~ was rough and some of the chondrocytes had proliferated
15 lightlylightly.

16 After the treatment ~~of~~with the Fengshiping, the inflammation of the
17 joint synovial membrane was inhibited, more ~~collagen~~collagen fiber was
18 produced; less synovial cells exfoliated ; the cells on the surface of the
19 cartilage had proliferated and the surface had turned smooth. The
20 cartilage was ~~on the~~in a recovering condition.

21 Experimental example 2: The effect of Fengshiping on the delayed
22 typed hypersensitivity reaction (DTH) caused by 2,4-DNFB
23 in(dinitrofluorobenzene) administered to the ear of the mouse

24 Fifty (50) NIH mice, half male and half female, were divided into 5
25 groups. Each mouse was ~~led to~~induced into hypersensitivity ~~reaetion~~by
26 ~~using the~~by application of 1% DNFB acetone solution ~~on the~~at a dosage

The immune and administration processes is as followingfollows:



Table 2.1 The effect of Fengshipping on the DTH caused by DNFB in the NIH mouse ($\bar{X} \pm S$)

group	dose (g/kg)	Administration time (day)	Mice number	Percent of ear swelling	Percent of inhibition (%)	P value
control			10	34.20±3.77		
Fengshipping	27	0~5	10	26.24±3.34	23.3	<0.01
Fengshipping	40	0~5	10	12.99±4.96	62.0	<0.01
Fengshipping	60	0~5	10	10.43±7.53	69.5	<0.01
cortisuman	0.003	0~5	10	13.93±4.41	59.3	<0.01
control			10	42.43±5.28		
Fengshipping	40	-2~0	10	31.50±10.52	25.0	<0.01
Fengshipping	40	-2~2	10	30.88±7.92	27.2	<0.01
Fengshipping	40	-2~5	10	21.07±4.62*	50.3	<0.01
Fengshipping	40	5~6	10	32.00±9.37	41.7	<0.01
cyclophosphane	0.05	-2~2	10	39.40±10.78	8.1	>0.05
cyclophosphane	0.05	-2~0	10	37.47±6.71	11.7	>0.05
control			10	38.50±4.67		
cyclophosphane	0.1×3	0、2、4 day once a day	10	23.00±7.65	40.3	<0.01
cyclophosphane	0.25	-3d	10	41.84±7.75	-8.7	
Fengshipping	60	0~4	10	27.20±10.20	29.4	<0.01
cyclophosphane +Fengshipping	0.25 + 60	-3,0~4	10	38.07±6.65	1.1	

* comparing with the other groups $P < 0.05$ 或 $P < 0.01$

1 ~~According to the~~The data showedshown in table 2.1, it indicated2.1
2 indicate that the Fengshiping had ~~aan~~ obvious ~~inhibitinginhibitory~~ effect
3 on the DTH caused by DNFB. There was a significant relationship
4 between the dosage and the effect. The ~~inhibitinginhibitory~~ activity
5 ~~increasesincreased~~ when the dosage ~~addsincreased~~. The ~~inhibiting~~
6 ~~percentinhibitory~~ effect could reach 69.5% ~~on theat~~ a dosage of
7 60.9g/kg.

8
9 **2.2 The effect on the DTH ~~ofwith~~ the different administration time**

10 The corresponding results from using different immune-inhibitory
11 compounds and administration processes ~~and the correspondent results~~
12 ~~had been showed in~~ are shown in the middle and bottom parts of ~~the~~ table
13 2.1. According to the results ~~showedshown~~ in the middle part of the table
14 2.1, all the different administration ways couldcan significantly inhibit
15 the DTH of the mouse ~~in spite of the administration beginning from the~~
16 ~~2 days before the sensitization and ending at the sensitization, or~~
17 ~~beginning from the 2 days before the sensitization and ending~~regardless
18 whether the administration began from 2 days before the sensitization to
19 the end of sensitization, or whether it began from 2 days before the
20 sensitization to 2 days after the end of sensitization, or beginning from
21 ~~the 2 days before the sensitization and ending~~whether it began 2 days
22 before the sensitization to 5 days after the end of sensitization, or
23 ~~beginning~~whether it began before the attack and ~~endingend~~ after the
24 attack. ~~But~~However, the administration ~~way~~ that began 2 days before the
25 sensitization and ended 5 days after the sensitization had the most
26 powerful ~~inhibitinginhibitory~~ activity. ~~It indicated~~The data indicate that
27 the Fengshiping could inhibit the DTH by ~~a compound mechanism that~~

1 ~~it could~~multiple mechanisms: it can inhibit the cells
2 ~~participate~~participating in the early period of the DTH, and it can inhibit
3 the effector cells in the ~~advanced~~latter period ~~and the~~as well as cells
4 related to the DTH in the middle period. This mechanism of inhibition
5 by Fengshiping was different from that of the cyclophosphane. ~~On~~Using
6 a small dosage, the cyclophosphane ~~didn't~~did not affect the DTH, if its
7 administration ~~way was beginning from the~~began 2 days before the
8 sensitization and ~~ending~~ended at the day of sensitization ~~day~~ or 2 days
9 after the day of sensitization ~~day~~.

10 Based on the bottom part of the table 2.1, if a high dosage of
11 cyclophosphane was ~~drenched~~given to the mouse ~~in at~~ one time 3 days
12 before the sensitization, the function of the Th (T helper) cells would
13 ~~turn~~become sthenic because of the powerful inhibition on the Ts
14 (suppressor T) cells. The DTH in the mouse would be enhanced. If the
15 cyclophosphane was used with the Fengshiping ~~on~~in this administration
16 ~~way~~method, it could lower the ~~inhibiting~~inhibitory activity of
17 Fengshiping. This result ~~indicated~~indicates that the Fengshiping ~~have~~has
18 a different ~~machnizm~~machnism compared to the cyclophosphane in the
19 control of DTH. ~~The~~ Fengshiping ~~maybe had~~may have a higher activity
20 in inhibiting ~~the THeells~~Th cells.

21
22 Experimental example 3: The effect on the humoral immunity

23
24 3.1 The effect on the ~~produce~~levels of the hemolysin antibody
25 ~~caused~~initiated by the ~~chick RBC~~CRBC (chicken red blood cells)

26 One hundred ninety (190) mice, 18-22g weight, half male and half
27 female, were divided into 19 groups. Each mouse was immunized with

0.2 ml of 5% CRBC solution-0.2 ml. The Fengshiping solutions were
drenched given orally to the mice at the different times. Seven (7) days
after the immunization, blood samples from all the mice were sampled
the blood taken from the eyes. Then the blood samples were diluted and
the levels of the hemolysin antibody were measured the level of the
hemolysin antibody. The results were showed are shown in table 3.1, 3.2
and 3.3.

**Table 3.1 The effect of Fengshiping on the produce levels of the
hemolysin antibody in the NIH mouse ($\bar{X} \pm S$)**

group	dose (g/kg)	Administration time	Mouse number	Hemolysin value	InhibitingInhi bitory percent (%)	P value
control			10	169.0±62.0		
Fengshiping	18	0~7	10	46.0±15.6	72.8	<0.01
Fengshiping	27	0~7	10	35.4±12.0	79.1	<0.01
Fengshiping	40	0~7	10	28.2±5.9	83.3	<0.01
Fengshiping	60	0~7	10	16.7±3.0	90.1	<0.01
Tripterygium hypoglaucom Hutch.	(Levl.) 13.3	0~7	10	121.0±88.0 **	28.4	<0.015
cyclophosphane	0.02	0~7	10	35.0±12.0	79.3	<0.01

** comparing with the Fengshiping (40g/kg) group P<0.01

**Table 3.2 The effect of Fengshiping on the produce levels of the
hemolysin antibody in the ICR mouse ($\bar{X} \pm S$)**

group	dose (g/kg)	Administratio n time	Mouse number	Hemolysin value	InhibitingInhi bitory percent (%)	P value
control	-	-	10	124.70±42.60		
Fengshiping	12	0~7	10	75.00±53.10	39.9	<0.05
Fengshiping	18	0~7	10	45.60±22.70	63.4	<0.01
Fengshiping	27	0~7	10	29.10±22.10	76.8	<0.01
Fengshiping	40	0~7	10	28.20±5.30	77.4	<0.01
Tripterygium hypoglaucom Hutch.	(Levl.) 6.0	0~7	10	143.50±67.90**		>0.05

cyclophosphane	0.02	0~7	10	27.80±6.60	77.9	<0.01
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**comparing with the Fengshipping (18g/kg) group P<0.01

Table 3.3 The effect of Fengshipping on the produce levels of the hemolysin antibody in the ICR mouse ($\bar{X} \pm S$)

group	dose (g/kg)	Administration time	Mouse number	Hemolysin value	Inhibiting Inhibit ory percent (%)	P value
control	-	-	10	256.0±26.0		
Fengshipping	18	-7~7	10	198.0±50.0	22.7	<0.01
Fengshipping	18	-3~7	10	156.0±85.0	39.1	<0.01
Fengshipping	18	0~7	10	98.0±35.0	61.7	<0.01
cyclophosphane	0.02	0~7	10	25.0±4.0	90.2	<0.01

According to the data in table 3, it ~~indicated that the~~ Fengshipping ~~had~~has a remarkable ~~inhibiting~~inhibitory effect on the produce levels of the hemolysin antibody in the different mouse species and this effect would increase along with ~~the an~~ increase of the dosage. There was a certain relationship between the dosage and the effect. The lowest effective dosage was 12g/kg. ~~Comparing~~Compared with the same quantity of Tripterygium hypoglaucum (Levl.) Hutch, the Fengshipping had a higher ~~inhibiting~~inhibitory activity. Based on the data in table 3.1, the ~~inhibiting~~inhibitory activity of Fengshipping was 2.25 times higher than the Tripterygium hypoglaucum (Levl.) Hutch. The ~~inhibiting~~inhibitory activity of Tripterygium hypoglaucum (Levl.) Hutch. ~~On with~~ the dosage of 13.5g/kg was weaker than that of the Fengshipping which ~~containing~~contains 6g/kg Tripterygium hypoglaucum (Levl.) Hutch).

3.2 The effect of the Fengshipping on the humoral immunity in the AA mouse

The NIH mice, 20±2g weight, were injected with 0.05 ml of FCA

under the ~~vola~~ skin of the right ~~postpedes~~ posterior limb. Three (3) weeks ~~late~~ later the AA model mouse ~~buildeed~~ was established. The model mice were divided into 6 groups randomly and ~~drenched with the~~ correspondent given orally the corresponding medicines for 5 days. At the beginning of the administration, all the mice were sensitized with 0.5ml of 10% sheep RBC (SRBC). Five days later, all the mice were killed. Their spleens were taken out and washed ~~by the~~ with Hank's ~~liquer~~ buffer to prepare the lymphocyte in suspended ~~liquor~~ solution. The concentration of the cells was adjusted to 2×10^7 / ml. One (1) ml of lymphocyte suspension, 1 ml of 0.2% SRBC and 1 ml of 1:30 addiment were added to one test tube. The tube was put in the water bath at 37°C for 1 hour. Then the tube was centrifugated at 2000rpm for 5 minutes. The supernatant fluid was separated and tested for its ~~spical~~ optical density at the 415nm wavelength on the ~~722 apectrophotometera~~ spectrophotometer. The value was ~~the represent~~ representative of PFC (plaque-forming cell) quantity.

The other ~~share~~ portion of the blood samples ~~got~~ from the sensitized mice was ~~separated~~ used to isolate the serum to test the potency of the antibody. The measured data were recorded ~~on the way of~~ using Log2 value. (See the data in table 3.4)

Table 3.4 The effect of Fengshiping on the humoral immunity in the mouse ($\bar{X} \pm S$)

group	dose (g/kg)	Mouse number	PFC (OD)	IgM(Log2)
control	-	8	0.819±0.013#	6.875±0.641
AA model group	-	10	0.940±0.019**	7.700±0.599*
fengshiping	5	8	0.834±0.012***#	6.875±0.641#

fengshiping	10	8	0.834±0.012**#	6.750±0.886#
fengshiping	20	8	0.830±0.014**#	6.375±0.518##
Glucosidorum Tripterygll Totorum	0.012	10	0.835±0.015**#	6.950±0.597#

Comparing with the control group *P<0.05, **P<0.01; comparing with the model group # P<0.05, ## P<0.01

According to the table 3.4, the levels of PFC and IgM in the AA mouse were higher than that of the normal mouse. ~~The Fengshiping could~~can lower the ~~produce~~levels of the PFC and IgM in the AA mouse significantly.

Experimental example 4: The effect of ~~the Fengshiping~~ on the passive ~~cutis~~cutaneous anaphylactic reaction (PCA) in the rat.

The rats were injected with the egg albumn at 10mg/kg in the muscle. At the same time, all the rats were injected with 2×10^{10} (0.2ml) bordetella pertussis in the abdominal cavity for sensitization. Two (2) weeks later, all the rats were killed to sample the blood. All the blood samples were separated ~~for preparing to obtain~~ the serum.

Sixty (60) rats, 150~200g, half male and half female, were divided into 6 groups at random. In the light narcosis condition induced by ~~aether ether~~, each rat was ~~cut the fleece in the~~shaved on its back and injected with the 2x 0.1 ml concentrations of anti-egg-album serum 0.1ml under the ~~skin at~~shaved area of the ~~fairless places~~skin. The serums were diluted ~~on the rates to~~concentrations of 1:5(d1) and 1:10(d2) before the experiment. Forty-eight (48) hours later, all the rats were ~~attaeked by~~ intravenous injecting the 0.5% evans intravenously injected with 0.5% Evans blue normal saline solution 1 ml which ~~containing~~contained 1 mg egg albumin. Twenty (20) minutes later, the rats were killed by decapitation. The skins on the rats' back ~~skin~~ were dissected and ~~turned over~~examined. According to the ~~dark and light~~dark and areal light areas of

the blue stains exudated from the vessels, all the rats were evaluated by several people. The ~~skins~~skins stained by the ~~evens~~Evans blue were scissored and soaked in 5ml of 0.1% sodium sulfate acetone (7:3) solution for 48 hours. Then it was ~~centrifugated~~centrifuged to separate the supernatant ~~liquor~~liquid. The optical density of the supernates ~~were~~was measured ~~the optical density~~ at the wavelength 590nm to calculate the degree of the PCA reaction and the ~~inhibiting~~inhibitory percent. The results were shown in table 4.

Table 4 The effect of Fengshiping on the PCA in rat ($\bar{X} \pm S$)

Group	dose (g/kg)	value		absorbancy	
		d ₁	d ₂	d ₁	d ₂
Control	-	5.60±1.78	2.40±2.46	0.191±0.129	0.096±0.106
Fengshiping	12	7.50±2.51	4.20±2.49	0.402±0.213*	0.192±0.175
Fengshiping	24	7.10±2.13	4.10±1.79	0.310±0.177	0.137±0.099
Fengshiping	48	6.00±1.83	1.70±1.95	0.121±0.109	0.024±0.026*
Tripterygium hypoglaucom (Levl.) Hutch.	8	6.11±1.27	2.56±1.67	0.223±0.122	0.074±0.045
Ketotifen	0.1	2.78±1.64**	0.67±1.41	0.033±0.024**	0.027±0.019*

Comparing with the control group *P<0.05 , **P<0.01

~~According to the~~The data in table 4, it ~~indicated~~indicate that the Fengshiping had a weak effect on the PCA in the rat. Only ~~on~~at a high dosage, was the ~~inhibiting~~inhibitory effect of Fengshiping ~~was~~ obviously different from that of the control group.

Experimental example 5: The effect of Fengshiping on the cytokines.

5.1 The effect of Fengshiping on the levels of TNF α and IL-2 in the mouse.

Sixty (60) ICR mice, 18~22g, half male and half female, were divided into 6 groups at random. Each group was ~~drenched~~of given

1 ~~orally~~ the ~~correspondent~~corresponding medicines including the different
2 dosages of Fengshiping and the other medicines. The medicines were
3 administrated once a day for 10 days. Twenty-four (24) hours after the
4 last administration, samples from the mice were sampled~~taken~~, including
5 ~~the macrophage~~macrophages and spleen cells from the abdominal cavity
6 in the aseptic condition. The samples were washed with Hank's liquor
7 ~~for 2 times~~buffer twice and with non-serum RPIM 1640 liquor ~~for 4~~
8 ~~time~~once. Then the washed samples were diluted to ~~the~~a suspension with
9 ~~the~~ 5% FCS-RPMI 1640 at ~~the~~a concentration of 2×10^8 cells / ml. Then
10 the suspensions were added with 10ng/ml LPS (lipopolysaccharide) or
11 the 10ng/ml ConA (concanavlin A) and cultured in the 5% CO2
12 condition for 48 hours at 37°C. Then the ~~cultured suspension were~~
13 ~~measured the~~ TNF α and IL-2 levels ~~on~~in the suspensions were
14 measured using the usual methods.

15 The measurement of TNF α

16 The ~~batten~~plate was coated ~~by~~with mouse TNF- α monoclonal
17 antibody. The ~~batten was added with the~~plate had cultured supernate
18 ~~on~~added at the dose of 50 μ l/~~hole~~well. Then the ~~batten~~plate was ~~put~~
19 ~~still~~incubated for 60 minutes at ~~the~~ room temperature. Then the
20 ~~batten~~plate was ~~added~~mixed with biotin-tagged antibody ~~mark~~marker at
21 25°C for 2 hours. Then the ~~enzyme labeled avidin~~avidin-tagged enzyme
22 (e.g., horseradish peroxidase, one that cleave or react against a detection
23 substrate) was added into the ~~batten~~plate and incubated for 30 minutes.
24 After adding the substrate ~~constant~~for the enzyme for 30 minutes, the
25 ~~batten was added with the stop liquor~~stop solution was added to the
26 plate. The mixed ~~liquor~~liquid was measured using the OD value at the

1 wavelength of ~~the~~ 450nm. The content of the TNF- α (ng/ml) was
2 calculated based on the ~~data of~~ OD value ~~by the method of~~ compared
3 with standard curve.

4 The measurement of the IL-2:

5 The CTLL (cytotoxic T lymphoid cells) cells which ~~was~~were on the
6 logarithmic growth phase and whose growth depends on ~~the~~ IL-2, were
7 adjusted ~~to the~~ in a suspension ~~at the~~ to a concentration of 1×10^5 cells/ml
8 with ~~the~~ 5% FCS-RPMI 1640. Then the 96-hole-well cell culturing
9 ~~batten were added~~ plate was filled with the CTLL cell suspension ~~on the~~
10 ~~quantity of~~ 100 μ l/hole. ~~The supernates were added on the quantity of~~
11 100 μ l/hole and each sample was added to 3 holes. The samples
12 ~~cultured~~ at a volume of 100 μ l/well. Each sample was added in triplicate.
13 To measure the concentration of IL-2, the cultured suspensions were
14 compared with ~~the~~ different dilutions of standard rHIL-2
15 ~~and~~ (recombinant human interleukin 2) in the control sample (culture
16 fluid) ~~to measure the IL-2.~~ All the samples were ~~cultured~~ incubated in
17 ~~the~~ 5% CO₂ for 24 hours at 37°C. Six (6) hours before the end of the
18 ~~culture~~ incubation, all the samples were centrifuged and separated from
19 the supernate. Each ~~hole were taken out~~ well had 110 μ l of supernate
20 removed and ~~added with~~ then 10 μ l of MTT was added to each well. The
21 samples were cultured for 3 hours at 37°C, and then the OD was
22 ~~measured the OD at the wavelength~~ wavelengths of 570nm and 630nm.
23 The final OD value of the sample was the difference of OD (570nm) and
24 OD (630nm).

$$\text{IL-2 activity} = \frac{\text{Sample OD} - \text{Control (Culture Fluid) OD}}{\text{Standard Sample OD} - \text{Control (Culture Fluid) OD}} \times \text{activity of the standard sample (IU/ml)}$$

Table 5.1 The effect of Fengshiping on the TNF α and IL-2 ($\bar{X} \pm s$)

group	dose (g/kg)	Mouse number	TNF (pg/ml)	IL-2 (IU/ml)
Control	-	10	87.80 \pm 14.63	26.30 \pm 4.22
Fengshiping	12	10	62.14 \pm 13.13**	16.00 \pm 2.89**
	24	10	58.60 \pm 9.63**	18.80 \pm 2.86**
	36	10	54.40 \pm 10.88**	18.20 \pm 2.86**
Tripterygium hypoglaucom (Levl.) Hutch. cyclophosphane	8 0.02	10 10	58.25 \pm 10.32** 42.20 \pm 9.57**	16.00 \pm 2.88** 10.10 \pm 3.00**

*P<0.05 , **P<0.01

~~According to the~~ The data in Table 5.1, it suggested 5.1 suggest that the Fengshiping have a has an obvious ~~inhibiting~~ inhibitory effect on the levels of TNF α . ~~On the~~ At a dosage of 12g/kg, the medicine had showed ~~ashown an~~ obvious ~~inhibiting~~ inhibitory effect. Along with the ~~With an~~ increase of ~~their~~ dosage, the ~~inhibiting~~ inhibitory effect ~~duly~~ increased. But the dosage-effect curve ~~went gently. There was~~ gradual. Fengshiping had an obvious ~~inhibiting~~ inhibitory effect on the levels of IL-2, ~~at but~~ no dosage-effect relationship was observed.

5.2 The effect of Fengshiping on the IL-1, IL-6

~~Seventy (70)~~ NIH mice, 18-22g weight, half male and half female, were divided into 7 groups at random. All the groups were ~~drenched~~ with the ~~correspondent~~ given orally the corresponding medicines (~~fengshiping~~ Fengshiping and the other medicines). The medicines were ~~drenched~~ given once a day for 10 days. ~~Twenty-four (24)~~ hours after the last administration, all the mice were killed and ~~sampled the~~

1 ~~macrophagemacrophages~~ and spleen cells from the abdominal carvity
2 ~~were sampled~~. The IL-1 and IL-6 in the samples were measured.

3 The measurement of IL-1:

4 The macrophages in the abdominal ~~earvitycavity~~ were sampled in
5 ~~the asepsisa sterile~~ condition. Then the samples were washed ~~by thewith~~
6 Hank's ~~liquer for 2 times~~buffer twice and nonserum RPMI1640 ~~liquer~~
7 ~~for 1 time~~media once. Then the ~~clearwashed~~ samples were adjusted to
8 ~~the 4×10⁶ cells / ml~~ cell suspension with 5% FCS-RPMI ~~liquermedia~~.
9 One (1) ml of the suspension was added to the test tube and cultured at
10 37°C for 1 hour. The ~~unadherentnonadherent~~ cells were
11 ~~abandoneddiscarded~~. Then ~~the cultured liquer was added with~~ 5% FCS-
12 RPMI 1640 and LPS (10ng/ml) were added to cell culture. The cells
13 were cultured in 5% CO₂ at 37°C for 72 hours. ~~During the~~
14 ~~course~~Afterwards, the cultured cells were freezed and thawed ~~for~~
15 several times. The final product was saved at 4°C. ~~The~~Thymuses from
16 C57 mice were ~~sampled the thymus in the asepsis~~obtained in sterile
17 condition. Then the samples were ~~prepared~~adjusted to the 1×10⁶ cells/ml
18 cell suspension with 5% FCS-RPMI1640.

19 One hundred (100) µl supernate separated from the ~~frost thawing~~
20 ~~liquer~~freeze-thawed solution and 100µl cell suspension of the thymus
21 were added ~~into theto~~ 96-~~holewell~~ flat bottom cell-culture ~~battenplates~~.
22 Each sample was cultured in 3-~~hole~~triplicate and compared with the
23 different dilutions of the standard rHIL-1 and the control sample (culture
24 fluid). Each ~~hole was added with~~well had 2ng ConA added and then the
25 ~~battenplate~~ was cultured in ~~the~~ 5% CO₂ at 37°C for 72 hours. Fourteen
26 (14) hours before the end of the culture, each ~~holewell~~ was added ~~with~~

1 3H-TdR (tritiated thymidine) at 0.1 μ Ci. The cultured cells were
2 collected with a multihead cell-harvesting apparatus and ~~measured the~~
3 cpm (count per minute) value was measured.

$$\begin{aligned} \text{IL-1 activity} = & \frac{\text{Sample cpm} - \text{Control (Culture Fluid) cpm}}{\text{Standard Sample cpm} - \text{Control (Culture Fluid) cpm}} \\ & \times \text{activity of the standard (ng/ml)} \end{aligned}$$

9 The measurement of the IL-6:

10 The spleen cells were sampled in the ~~asepsis~~ sterile condition. Then
11 the samples were washed ~~by the~~ with Hank's liquor ~~for 2 times~~ buffer
12 twice and nonserum RPMI1640 liquor ~~for media~~ 1 time. Then the clear
13 samples were adjusted to ~~the~~ 2×10^6 cell/ml cell suspension with 5%
14 FCS-RPMI liquor media. One (1) ml of the suspension was added to ~~the~~ a
15 round-bottom centrifuge tube. After adding the ConA (10ng/ml), the
16 samples were cultured in ~~the~~ 5% CO₂ at 37°C for 72 ~~hour~~ hours.

17 The MH60 cells, ~~which grew depending on the~~ their growth
18 dependent on IL-6 and ~~were on~~ at the logarithmic growth stage, were
19 adjusted to ~~the~~ 1×10^5 cells/ml cell suspension with the 5% FCS-
20 RPMI1640.

21 The 96-~~hole~~ well flat bottom cell culturing ~~batten~~ plate was added
22 ~~with the~~ MH60 cell suspension ~~on the quantity of~~ at 100 μ l/hole well and
23 the culturing ~~supernates~~ suspension of spleen cells at 25 μ l/hole well. Then
24 the ~~fluid~~ volume in each hole well was adjusted to ~~the~~ 200 μ l with ~~the~~ 5%
25 FCS-RPMI 1640. Each sample was cultured ~~with 3 copies~~ in triplicate
26 and compared with ~~the~~ solutions at different ~~solutions~~ concentrations of
27 standard rHIL-6 and the pure culturing fluid. The ~~batten~~ plate was

~~cultured~~incubated in 5%CO₂ at 37°C for 72 hours. ~~Six (6)~~ hours before the end of the ~~culture~~incubation, the samples were centrifuged. ~~Each hole-~~In each well, 110µl of the supernate was sucked out ~~the supernate~~ ~~110µl~~ and 10µl of MTT was added ~~the MTT 10µl~~. The samples were kept at 37°C for 3 hours. And then ~~they were measured~~ the OD at the wavelength 570nm and 630nm were measured. The final OD value = OD 570nm – OD 630nm.

$$\text{IL-6 activity} = \frac{\text{Sample OD} - \text{Culturing Fluid Control OD}}{\text{Standard Sample OD} - \text{Culturing Fluid Control OD}} \times \text{Sample Dilution} \times \text{Activity Of The Standard (IU/ml)}$$

Table 5.2 The effect of Fengshiping on the IL-1, IL-6 ($\bar{X} \pm S$)

Group	Dose (g/kg)	Mouse number	IL-1 (ng/ml)	IL-6 (IU/ml)
Control	-	10	78.7±7.1	94.6±6.8
	7.5	10	59.3±4.9**	64.9±4.8**
Fengshiping	15	10	53.3±5.7**	60.5±4.3**
	30	10	54.4±4.8**	56.0±4.6**
	60	10	47.0±16.6**	56.6±6.1**
<i>Tripterygium hypoglaucom</i> (Levl.)	5	10	57.6±4.7**	65.7±4.9**
Hutch. cyclophosphane	0.02	9	44.5±7.7	49.6±6.7**

Based on the data in the table 5.2, ~~the~~ Fengshiping had an ~~abvious~~ ~~inhibiting~~obvious inhibitory effect on the macrophage in producing of IL-1 and spleen cell in producing IL-6. ~~Along with the~~ With increase of ~~thein~~ dosage, the effect is duly enhanced ~~too~~.

5.3 The effect of Fengshiping on the plasma NO (nitric oxide) in the AA

1 rat

2 Sixty (60) SD rats, 160 ~ 220g weight, half male and half female,
3 were divided into 6 groups. The rats in the blank control group were
4 injected ~~the NS~~with 0.5ml of NS (normal saline) under the skin of the
5 right ~~postpede-vela~~posterior hindlimb. Other rats were injected with
6 ~~the 0.5ml of FCA~~ 0.5ml at the same place as that of the control group.
7 Eighteen (18) days later, the AA model was ~~built~~established. Then the
8 rats were ~~drenched~~given orally the ~~correspondent~~corresponding
9 medicines or ~~the~~ distilled water once a day for 5 days. Three (3) groups
10 were ~~drenched~~given orally the solution of Fengshiping ~~on the~~ at high,
11 middle and low dilution. The positive control group was ~~drenched~~
12 ~~with~~given orally Glucosidorum Tripterygll Totorum. The blank control
13 group and the model group were ~~drenched with the~~ was given orally
14 distilled water of the same ~~volume~~volume. One (1) hour after the last
15 administration, 2 ml of each rat ~~was sampled the's~~ blood from the
16 abdominal aorta ~~for 2 ml was sampled~~. The plasma of the blood samples
17 ~~werewas~~ separated and saved at - 70°C for ~~the~~ measurement. The
18 measurement of NO was done ~~on the direction of the NO reagent~~. 0.1ml
19 ~~plasma was added in 0.6ml reagent C and 0.4ml double distilled water.~~
20 ~~After the mixture shaken up, it was added in 0.1ml reagent D and~~
21 ~~cultured on the ice for 60 min. Then it was centrifuged at 12000 rpm for~~
22 ~~2 min. The supernate was separated. 0.6 ml supernate was mixed with~~
23 ~~0.4ml double distilled water and 0.1ml reagent A, and then it was~~
24 ~~cultured in the ice water for 15 min. Then the mixture was added in~~
25 ~~reagent B 0.1ml and put at the room temperature for 1 hour. Then the~~
26 ~~new mixture was measured the OD at the wavelength 545nm~~ as per the

directions of standard NO-detection kit. Based on the OD value of the sample, the content of NO was calculated on the standard curve. (See the result in table 5.3)

Table 5.3 The effect of Fengshiping on the plasma NO level in the AA rat ($\bar{X} \pm S$)

Group	Dose (g/kg)	Rat number	Content of NO ($\mu\text{mol/L}$)	y ($y=Lgx$)
Control	-	8	13.55 \pm 1.11*	1.131 \pm 0.032
AA model	-	9	17.56 \pm 4.15	1.235 \pm 0.097
Fengshiping	12	7	9.83 \pm 2.58*** $\Delta\Delta$	0.985 \pm 0.087
Fengshiping	24	7	10.12 \pm 1.56*** $\Delta\Delta$	1.001 \pm 0.067
Fengshiping	48	7	10.70 \pm 1.51*** $\Delta\Delta$	1.026 \pm 0.062
Glucosidorum Totorum	Tripterygll 0.006	7	15.25 \pm 3.48	1.173 \pm 0.099

Comparing to the model group* $P < 0.05$, ** $P < 0.01$; comparing to the Glucosidorum Tripterygll Totorum $\Delta\Delta P < 0.01$

Based on the data in table 5.3, the NO level was higher in the model group than in the blank control group. The Fengshiping had an obvious effect on lowering the NO level in the AA rat. The Glucosidorum Tripterygll Totorum had the similar effect but its effect was weaker than that of the Fengshiping.

Experimental example 6 : The effect of Fengshiping on the T lymphocyte, CD₄, CD₈ and NK cells in the mouse.

6.1 The effect of Fengshiping on the transform—of lymphocyte transformation of lymphocytes in the normal mouse.

Eighty (80) NIH mice, half male and half female, were divided into 8 groups randomly and ~~drenched with the correspondent~~ given orally the corresponding medicines once a day for 10 days. Twenty-four (24) hours

after the last administration, all the mice were killed to sample the spleen cells aseptically. Then the samples were washed ~~by the~~with Hank's liquor ~~for 2 times~~buffer twice and nonserum RPMI1640 liquor ~~for 1 time~~media once. Then the ~~clear~~washed samples were adjusted to the 2×10^6 cells/ml cell suspension with 5% FCS-RPMI liquormedia. The 96-holewell flat bottom cell culturing ~~batten~~plate was added ~~with~~ the cell suspension ~~on the quantity~~at a volume of 100 μ l/holewell. Each sample was cultured ~~with 3 copies~~. 2 holesin triplicate. Of the triplicate, two (2) wells were added ~~in~~ 2ng of ConA each as the stimulating reagent. The ~~other hole~~third well was not added ~~in the~~ given ConA and ~~was~~ kept as the control holewell. The ~~batten~~plate was ~~cultured~~incubated in 5% CO₂ at 37°C for 72 hours. Fourteen (14) hours before the end of the ~~culture~~incubation, each ~~hole~~ ~~was added~~ ~~in~~well had 3H-TdR 0.1 μ Ci added. The cells were harvested ~~by using~~ the multihead cell harvesting instrument and ~~were~~ measured ~~the~~ ~~for their~~ cpm-value. The average value ~~value~~cpm and the stimulating index of the different groups were compared directly. The stimulating index was calculated as followingfollows:

$$\text{Stimulating Index} = \frac{\text{Stimulated cpm}}{\text{Control cpm}}$$

See the result in ~~ta~~table 6.1

Table 6.1 The effect of Fengshiping on the ~~lymphocyte~~lymphocyte transformation induced by ConA in the mouse ($\bar{X} \pm S$)

Group	Dose (g/kg)	Mouse number	cpm	Stimulating index
Control	-	10	20433 \pm 3579	25.87 \pm 3.06
Fengshiping	7.5	10	13566 \pm 1779**	27.29 \pm 7.67
	15	10	12708 \pm 1692**	18.04 \pm 3.76

	30	10	12809±2575**	16.17±4.37
	60	10	12090±1706**	19.05±3.80
<i>Tripterygium hypoglaucum</i> (Levl.)	2.5	10	18038±3359	17.11±2.60
Hutch.	5	10	12081±1039**	17.58±4.37
Cyclophosphane	0.02	9	9922±1145**	13.66±2.28

1 Comparing to the control group*P<0.05 , **P<0.01

2 ~~According to the~~The data in table 6.1, it indicated6.1 indicate that
3 ~~the~~Fengshiping had an obvious ~~inhibiting~~inhibitory effect on the
4 lymphocyte transformation and there was a dosage-effect relationship.

5 6.2 The effect of Fengshiping on the CD₄, CD₈ and NK cells

6 The experiment was same ~~to as~~ the experiment described in 5.1.
7 Twenty-four (24) hours after the last administration, the spleen cell
8 samples were made into ~~the a~~ 2×10⁸ cells/ml cell suspension with 5%
9 FCS-RPIM1640. The quantity of CD₄, CD₈, NK cells and the rate
10 CD₄/CD₈ were measured ~~on by~~ the usual method.

11 The measurement of CD₄ and CD₈:

12 ~~The~~Fifty (50) µl of the spleen cell suspension-~~50µl~~ was added ~~on~~
13 ~~the to a~~ glass to ~~made~~smear the cell-smear. The glass had been coated by
14 ~~the with~~ polylysine. The T cell of the mouse was set as the positive
15 control sample. The cell smear was enveloped by the serum of the
16 normal mouse after it was fixed ~~by the with~~ acetone. Then the enveloped
17 sample was ~~added~~incubated with ~~the antibody of~~antibodies to CD₄ and
18 CD₈ ~~which were marked by the~~tagged with hominine biotin. It was
19 incubated at 37°C for 2 hours. Then ~~the sample was added with the~~
20 ~~avidin labeled by enzyme and put still~~avidin-tagged enzyme enzyme
21 (one that can cleave or react against a detection substrate) was added to
22 the sample and incubated for 10 min. After ~~added with the~~ substrate was
23 added for 10 min, the mixed sample was washed and dyed with ~~the~~
24 hematoxylin for 2 min. Then the sample was ~~dyhydrated~~dehydrated with

the grade-alcohol and enveloped with gelatin-~~glycetrol~~-glycerol. Two hundred (200) cells in the smear were chosen as ~~the research target~~ to be evaluated under the high power microscope.

$$\text{Content Of Cell} = \frac{\text{Dyed cell number}}{200} \times 100\%$$

The measurement of the NK cell:

The preparation of the EC cell: The spleen cells were sampled in ~~the asepsis~~sterile condition. Then the samples were washed ~~by the~~ with Hank's liquor for 2 ~~times~~buffer twice and nonserum RPMI1640 liquor for 1 ~~time~~media once. Then the clear samples were adjusted to ~~the~~ 2×10^8 cells/ml cell suspension with 5% FCS-RPMI ~~liquor~~media. This cell suspension was used as the EC.

The preparation of the TC cell: The Yack-1 cells, which were sensitive to the mouse NK cell and ~~engrowing~~ at the logarithmic ~~growth~~ phase, were adjusted to ~~the~~ 4×10^4 cells/ml cell suspension. ~~It~~ This cell suspension was used as the TC.

Measurement: EC and TC, One hundred (100) μl each were added into the 96-~~hole~~well flat bottom cell culturing ~~batten~~plate. Each sample was cultured in triplicate with ~~3 copies and set~~ 2 control samples: EC and TC. (EC control: EC100 μl + 5% FCS RPMI 1640 100 μl ; TC control : TC100 μl + 5% FCS RPMI 1640 100 μl). The samples were ~~cultured~~incubated in 5% CO₂ at 37°C for 24 hours. Six (6) hours before the end of the ~~culturing~~incubation, the samples were centrifuged and ~~sucked out~~ 110 μl supernate were aspirated out of each ~~hole~~well. And then ~~the holes~~ 10 μl of MTT were added ~~in the~~ MTT 10 μl to each well.

1 After ~~put~~incubating at 37°C for 3 hours , the OD values of the mixed
2 samples were measured ~~the OD value at the wavelength~~wavelengths of
3 570nm and 630 nm. The OD of each ~~hole~~well = OD570nm - OD630nm.

4

5

$$\text{Activity Of NK} = \left(1 - \frac{\text{Sample } \overline{\text{OD}} - \text{EC Control } \overline{\text{OD}}}{\text{TC Control } \overline{\text{OD}}} \right) \times 100 \%$$

Table 6.2 The effect of Fengshiping on the CD4, CD8, NK cell ($\bar{X} \pm S$)

Group	Dose (g/kg)	Mouse number	CD4 (%)	CD8 (%)	CD4/CD8	NK
Control	-	10	20.80±2.94	14.80±2.49	1.42±0.18	40.13±4.89
Fengshiping	12	10	19.14±2.91	13.43±2.51	1.43±0.08	31.94±4.52*** [△]
	24	10	17.30±2.51**	12.00±2.40	1.46±0.16	35.36±3.40*** [△]
	36	10	16.30±2.50**	11.23±2.94**	1.49±0.20	31.06±3.53*** [△]
<i>Tripterygium Hutch.</i>	8	10	16.25±2.25**	11.50±2.45	1.44±0.18	32.20±2.00**
Cyclophosphane	0.02	10	11.50±2.50**	4.10±1.20**	2.91±0.53**	23.10±3.66**

Comparing to the control group *P<0.05 , **P<0.01 ; comparing to the cyclophosphane[△] P<0.01

1 According to the table 6.2, ~~it is~~Fengshiping had some inhibitory
2 effect on CD₄ cells and CD₈ cells. There was a relation between the
3 ~~dosage~~dosage and the effect, but the dosage-effect curve was
4 ~~smooth~~gradual. The effective dosage of Fengshiping on the
5 ~~inhibiting~~inhibition of CD₄ was 24g/kg. The minimum effective dosage
6 on inhibiting the CD₈ was 36g/kg. ~~As the rate of CD₄/CD₈, the~~
7 Fengshiping had no obvious effect. on the ratio of CD₄/CD₈.
8 Cyclophosphane had an obvious effect ~~on the~~ inhibiting ~~of the~~ both
9 kind of cells, and with the ~~inhibiting~~inhibitory effect on the CD₈ was
10 very ~~powerful~~potent, which could increase the ~~rate~~ratio of CD₄/CD₈
11 ~~magnificent~~significantly.

12 As for NK cell, ~~the~~ Fengshiping had a remarkable
13 ~~inhibiting~~inhibitory effect, but the dosage-effect relationship was not
14 certain. ~~As the same while, the~~Similarly, cyclophosphane had shown an
15 obvious ~~inhibiting~~inhibitory effect on the NK cell. ~~On the~~At a dosage of
16 20mg/kg, the ~~inhibition~~inhibitory effect of cyclophosphane was
17 significantly different from that of ~~the~~ Fengshiping ~~on the~~ at its 3
18 dosages: 12, 24 and 36g / kg.

19 6.3 The effect on the transformation and function of the T 20 ~~lymphocyte~~lymphocyte in the AA mouse.

21 NIH mice, 20±2g weight, were injected with 0.05 ml of FCA under
22 the skin of the right ~~postpede~~ volaposterior limb to build the AA model.
23 The mice in the control group were injected with 0.05ml NS at the same
24 place. Three (3) weeks later, after the AA model was built, all the mice
25 were ~~drenched~~given orally the ~~correspondent~~corresponding medicines
26 once a day for 5 days. Five (5) days later, all the mice were sampled, and

the blood was used to make ~~the blood smears~~smears. The smears were dyed by ~~the~~ esterase. Then the smears were observed under ~~the an~~ oil immersion lens to calculate the percent of the positive-dyed cells (it represented the content of the T cells in the blood). The spleen cells of the mice were sampled ~~the spleen cells in the condition of~~while the mice were under anaesthesia and then the cell samples were prepared ~~to the single~~in a cell suspension. The cell suspension was washed by PBS and then its supernate ~~were abandoned~~was discarded. The rest ~~part was~~ added ~~with~~had 4 ml of blood ~~eytolysate~~4ml cell lysate added. The mixed sample was ~~shaked~~shaken for 2 ~ 3 min to ~~solute~~solubilize the RBC. After the RBCs were ~~destroyed~~solubilized, the sample was centrifuged to separate and ~~abandon~~discard the supernate. The sample without supernate was washed ~~by~~with the luminescence ~~lotion for 2 times~~solution twice. Then it was centrifuged to separate and ~~abandon~~discard the supernate. In the next step, the sample was adjusted to the 1×10^6 cells/ml cell suspension. Each tube was added ~~with~~50 μ l of diluted antibody ~~o~~to CD₄ and CD_{8₈}. Then the ~~tub~~stubes were ~~cultured~~incubated at 4°C for 1 hour. After the culture, the samples were washed with the luminescence ~~lotion for 2 times~~solution twice and ~~added in~~2ml of the fixing fluid ~~2 ml was added~~. After fixing, the samples were filtrated through the 400-mesh screen to the FCA tube. The filtrated samples were analyzed by ~~the~~ flow cytometer (FCM). The result ~~was~~is shown in ~~the~~ table 6.3.

Table 6.3 The effect of Fengshipping on the T cell in the AA mouse

$(\bar{X} \pm S)$						
Group	Dose	ANAE+	CD4+	CD8 ₈ +	CD4+/CD8+	

	(g/kg)	(%)	(%)	(%)	
Control	-	50.60±4.25	26.13±1.16	15.56±0.68	1.68±0.03
AAmodel	-	49.00±4.22 [*]	32.56±2.87 ^{**}	13.59±1.03 ^{**}	2.49±0.16 ^{**}
	7.5	49.13±4.03 [*]	27.30±1.76 ^{##}	15.98±1.11 ^{##}	1.71±0.04 ^{##}
Fengshiping	15	49.31±3.29 [*]	27.96±1.67 ^{##}	16.23±1.27 ^{##}	1.73±0.05 ^{##}
	30	48.56±3.23 [*]	26.75±1.94 ^{##}	15.58±1.29 ^{##}	1.72±0.04 ^{##}
Glucosidorum Tripterygll Totorum	0.012	48.88±2.89 [*]	27.88±1.99 ^{##}	16.33±1.31 ^{##}	1.70±0.03 ^{##}

1 n=8 , comparing with the control group*P<0.05 , **P<0.01 ;
2 comparing with the model group# P<0.05 , ## P<0.01 ; comparing with
3 the control group[▲]P>0.05

4 According to the data in table 6.3, there was no significant
5 difference in the different groups on the ANAE (alpha-naphthyl acetate
6 esterase) positive cell. But in the AA mouse, the increase of the CD₄ was
7 significant, while the decrease of CD₈ was significant too. So the
8 rateratio of CD₄/CD₈ had a remarkable increase. The result
9 indicatedindicates that~~the~~ Fengshiping could adjust the CD₄, CD₈ and
10 CD₄/CD₈ to the normal range.

11 Experimental example 7: The effect of Fengshiping on the
12 phagocytic function of the macrophage in the mouse abdominal cavity.

13 Fifty (50) NIH mice, 18~ 22g weight, half male and half female,
14 were divided into 5 groups and ~~drenched with the correspondent given~~
15 orally the corresponding medicine solutions ~~on~~at the same
16 ~~volume~~volume. The administration was once a day for 7 days. One (1)
17 hour after the last administration, all the mice were injected with 0.2ml
18 10 % chick RBC into the abdominal ~~cavity~~cavity. Four (4) hours later,
19 all the mice were killed and ~~sampled~~the fluid in the ~~abdominal~~
20 ~~cavity~~abdominal cavity was sampled. The ~~liquor~~liquid samples were

~~dropped~~deposited on the glass and ~~counted~~—the number of the
macrophage ~~which~~macrophages was counted that had phagocytized the
CRBC and the number of the CRBC in ~~one~~each macrophage was also
counted. (See the result in table 7)

**Table 7 The effect of Fengshiping on the CRBC phagocytosis
function
of the macrophage in ICR mouse abdominal cavity ($\bar{X} \pm S$)**

group	dose (g/kg)	Mouse number	Percent of phagocytosis (%)	phagocytosis index
Control	-	10	25.75±9.40	1.28±0.20
Fengshiping	27	10	33.20±12.77	1.46±0.36
Fengshiping	40.5	10	35.20±10.16	1.21±0.20
Fengshiping	60.9	10	37.78±20.14	1.53±0.32
dexamethasone	0.005	10	8.33±10.13*	1.10±0.18

*P<0.05

According to the table 7, ~~the~~Fengshiping had no obvious effect on
the ~~phagocytosis~~phagocytotic function of the macrophage in the mouse
abdominal cavity.

Experimental example 8: The effect of Fengshiping on the
hyperfunction of the capillary permeability in the mouse abdominal
cavity.

Ninety (90) NIH mice, 18~22g weight, half male and half female,
were divided into 9 groups and ~~drenched with~~given orally the

~~correspondent~~corresponding medicine solutions of the same ~~volume~~volume. The medicines were ~~drenched~~given once a day for 3 days or just 1 time. One (1) hour after the last administration, each mouse ~~were~~was injected with 0.7% HAC (acetic acid) – NS solution into the abdominal cavity. At the same time, each mouse was injected with the 0.5% Evans blue – NS solution into the vessel ~~on the~~at a dose of 0.1ml/10 g. Thirty (30) min later; all the mice were killed by cervical ~~disjoint~~dislocation. The abdominal cavity was opened and washed ~~by~~ thewith 5ml NS. The NS used was collected and adjusted to a volume of 8ml by ~~the~~ pure NS to be used as the sample. The samples were centrifuged at 3000 rpm to get the supernate. The supernate OD was measured ~~the OD~~ at the wavelength at of 590nm. (See the result in table 8)

Table 8 The effect of Fengshiping on the hyperfunction of the capillary permeability induced by the acetic acid in the mouse abdominal cavity ($\bar{X} \pm S$)

Group	Dose (g/kg)	Administration	Mouse number	Leakage of the tincture (OD)	P value
Control	-	-	10	0.29±0.13	
Fengshiping	27	qd×1	10	0.26±0.14	>0.05
Fengshiping	40	qd×1	10	0.25±0.10	>0.05
Fengshiping	60	qd×1	10	0.25±0.09	>0.05
Control	-	-	10	0.28±0.15	
Fengshiping	27	qd×3	10	0.25±0.12	>0.05
Fengshiping	40	qd×3	10	0.18±0.10	<0.05
Fengshiping	60	qd×3	10	0.15±0.13	<0.05
dexamethasone	0.15	qd×3	10	0.11±0.07	<0.01

~~According to the~~The data in table 8, ~~it indicated~~8 indicate that Fengshiping could obviously inhibit the hyperfunction of the capillary permeability induced by the acetic acid in the mouse abdominal cavity if

1 ~~if the mouse~~ was ~~drenched~~ given the medicine for 3 days continuously. If
2 the medicine was ~~drenched~~ given for just ~~1 time~~ once, the inhibiting effect
3 was not obvious.

4 Experimental example 9: The effect of Fengshiping on the pleuritis
5 exudation and aggregation of the inflammatory cell ~~aggregation~~ induced
6 by the carrageenan.

7 The mice were divided into 5 groups at random and injected with
8 0.5% Evans blue NS solution into the caudal vein ~~on the~~ at a dosage of
9 0.1ml/10g. Then the mice were injected with the 0.03ml 1% carrageenan
10 in the right chest cavity with ~~the special syringe niddle~~. 4a syringe needle.
11 Four (4) hours and 32 hours after the injection, the
12 ~~correspondent~~ corresponding mice were killed and ~~open~~ the
13 ~~abdominal~~ had their abdominal cavity opened to expose the diaphragm.
14 Two (2) ml of the ~~lotions~~ solution were injected to the chest cavity ~~by 2~~
15 ~~times~~ twice with a 1 ml injector. The ~~lotions~~ solution was collected and
16 saved in a test tube. Twenty (20) μ l of the ~~lotions~~ solution collected was
17 added into the 400 μ l WBC dilution. The WBC in the mixed dilution was
18 counted under the microscope. The rest of the ~~lotions~~ solution was
19 centrifuged at 3000rpm for 10 min. The supernate ~~of the lotion~~ was
20 measured ~~the~~ for its OD at ~~the~~ a wavelength of 600nm. The OD value of
21 the sample should be corrected with the correspondent OD value of the
22 pure ~~lotions~~ solution. (See the result in table 9)

23
24 **Table 9 The effect of Fengshiping on the inflammatory cell**
25 **aggregation induced by the carrageenan ($\bar{X} \pm S$)**

Group	Dose (g/kg)	WBC number(2×10^5)		Tincture exudation (OD)	
		4h	32h	4h	32h

Control	-	46.0±6.9	16.0±9.6	0.156±0.066	0.109±0.019
Fengshiping	27	26.8±4.5*	14.2±8.0	0.121±0.062	0.116±0.031
Fengshiping	40.5	10.9±4.0**	17.3±4.6	0.100±0.048	0.153±0.032
Fengshiping	60	8.0±5.5**	6.6±4.7*	0.129±0.066	0.092±0.051
dexamethasone	0.05	12.7±10.2**	4.4±4.0*	0.085±0.045	0.063±0.017

*P<0.05 , **P<0.01

~~According to the~~ The data in table 9, it indicated ~~9 indicate~~ that the Fengshiping had an obvious ~~inhibiting~~ inhibitory effect on the inflammatory cell aggregation. The effect was powerful at the early stage. The regression equation on the data of the fourth hour was as ~~following~~ follows: $y=44.13 - 2.01x$, $r= - 0.9625$. The effect ~~on~~ at the late stage was weak. At the high dosage of 20g/kg, the medicine could affect the aggregation of the WBC. But it had no obvious effect on the pleuritis exudation.

Experimental example 10: Effect on aggregation of ~~leucoeyte~~ leukocyte in rats² with a sac of CMC sae(carboxymethylcellulose).

Sixty four (64) SD rats, 150-180g weight, half male and half female, were randomly divided into 8 groups, ~~which~~ and they were ~~drenched with~~ given orally the same volume ~~and~~ but different dosage of drug liquid once a day, ~~lasting for~~ for 3 days. A day before experiment, rats were injected with 20ml 1% CMC solution into the sac at the rat's back ~~caused~~ created by 20ml air injection before the experiment. ~~3.5 hour~~ Three and a half hours and 7.5 ~~hour~~ hours later, 0.1ml of liquid in the sac was extracted each time, and was colored ~~in~~ with 0.01% brilliant cresyl blue solution. ~~leucoeyte was~~ and leukocytes were counted in the sac ~~liquer~~ liquid under a microscope. The results ~~showed~~ are shown in the table 10.

Table 10 effect on leucocyte counts of carboxymethyl cellulose sac of rats with Fengshiping ($\bar{X} \pm S$)

groups	dosage (g/kg)	rats number	WBC count($\times 10^7/L$)	
			3.5 hrs	7.5 hrs
control	-	8	9.7 \pm 4.2	57.7 \pm 17.3
Fengshiping	27 \times 1	8	8.5 \pm 3.5	39.4 \pm 16.5
Fengshiping	40 \times 1	8	8.7 \pm 7.3	35.3 \pm 23.2
Fengshiping	60 \times 1	8	6.6 \pm 3.3	18.1 \pm 8.6**
Control	-	8	10.97 \pm 6.7	35.6 \pm 11.2
Fengshiping	27 \times 3	8	15.4 \pm 9.7	38.6 \pm 15.5
Fengshiping	40 \times 3	8	4.8 \pm 3.4**	18.4 \pm 12.2**
Fengshiping	60 \times 3	8	3.0 \pm 2.8**	11.0 \pm 9.2*
cortisone	0.1 \times 3	8	14.2 \pm 8.0	41.7 \pm 16.0
Control	-	8	10.9 \pm 3.0	41.3 \pm 6.9
Fengshiping	18 \times 7	8	6.2 \pm 3.0*	11.4 \pm 6.4*
Fengshiping	27 \times 7	8	3.7 \pm 1.7**	6.4 \pm 3.1**
Fengshiping	40 \times 7	8	2.5 \pm 1.9**	5.9 \pm 3.9**
cortisone	2mg \times 1	8	1.5 \pm 0.7**	3.0 \pm 1.0**

Compared with control group**P<0.01

According to the table 10, the Fengshiping could inhibit significantly aggregation of leucocyte in the rats' CMC-sac containing CMC, and the inhibition showed apparent dosage-effect relation correlation, which was stronger as with greater frequency of administration time lasted. With administration of continuing seven days, wandering the migration of leucocyte could be inhibited significantly at dosage of 18g/kg, at the same time. Similarly, there was also very strong inhibition with cortisone injection into the sac.

Experimental example 11: The effect on croton oil-induced swelling in the ears of mice.

Sixty (60) NIH mice with weight of 18~22g, male and female accounting for half and half, were divided into 6 groups, which were drenched given orally with the same volume and different dosage of drug liquid or tragacanth liquid, once a day, lasting 3 days. One (1) hour after

the final administration, 2% croton oil mixture of 0.02ml was embrocated uniformly on ~~the~~ both sides of ~~the~~ left ears of ~~the~~ mice, and after 4 hours, the mice were ~~snapped off itsput to death by snapping their~~ cervical vertebra ~~and put to death~~. The left and right ears were cut down, then ~~inflammatory~~ the inflamed and control ears were ~~weighted~~ weighed by certain means. ~~Difference of~~ Differences in weight between left and right ears ~~was reflect~~ the swelling extent of the swelling of the inflamed ears, with results showingshown in table 11.

Table 11 ~~effect~~ Effect on croton oil-induced swelling of the ears of mice with Fengshiping ($\bar{X} \pm S$)

Groups	dosage (g/kg)	rats number	Degree of ears' swelling (mg)	inhibition rate (%)	P value
Control group	-	10	44.38±9.40		
Fengshiping	27	10	39.05±12.33	12.00	>0.05
Fengshiping	40	10	36.65±5.83	17.64	<0.05
Fengshiping	60	10	34.91±9.71	21.34	<0.05
dexamethasone	0.003	10	14.13±5.75	68.16	<0.01

~~It was~~ As seen from table 11, ~~that~~ Fengshiping had remarkable inhibition to croton oil-induced swelling of the ears of mice, and had ~~quantity~~ dosage-effect relation correlation, but ~~which~~ the curve was ~~gentle~~ and smooth gradual. There was significant inhibition effect at 13.5g/kg of dosage.

Experimental example 12: Effect on acetic acid-induced twisting reaction of mice.

Sixty (60) Kuming mice with weight of 18 ~ 22g, male and female accounting for half and half, were randomly divided into 6 groups, which were ~~drenched~~ given orally different dosages of drug liquid or ~~Xihuange~~ itrageacanth solution. One (1-hours) hour after administration, 0.2ml of 0.7% HAC saline of 0.2ml solution was injected, sc

(subcutaneous), and the mice were placed in ~~aquarium and observed~~
enclosure and observed for the length of the latent period before the
twisting reaction of each mouse and the twisting times in 20 minutes;
with the results ~~showingshown~~ in table 12:

**Table 12 The effect of Fengshiping on acetic acid-induced twisting
reaction of mice ($\bar{X} \pm S$)**

groups	dosage (g/kg)	Rats numbers	Twisting times	Latent time (minute)
Control	-	10	34.6±14.1	3.13±0.80
Fengshiping	27	10	28.2±5.76	3.82±0.85
Fengshiping	40	10	31.0±18.4	3.86±2.00
Fengshiping	60	10	20.7±12.3*	3.95±1.42
Tripterygium hypoglaucum (Levl.) Hutch.	20	10	25.1±11.9	3.60±0.93
morphine hydrochloride	10mg/kg	10	0.0±0.0	0.00±0.00

~~It was seen~~The data from table 12 indicate that large ~~dosedoses~~ of
Fengshiping could delay the latent time before the HAC-induced
twisting reaction and significantly reduce the twisting times in 20
minutes, which indicated Fengshiping had the effect of
~~abirritation~~aberration in some degree.

Experimental example 13: Effect on hemorheology of AA rats,

Each ~~of~~ SD (Sprague Dawley) rats, 180±20g weight, were injected
intracutaneously with 0.05ml Freund's complete adjuvant on the right
back foot metatarsal, and they were developed into adjuvant arthritis
models. Each of the rats of negative control group were injected
intracutaneously with 0.05ml ~~saline~~saline on the right back foot
metatarsal. Three weeks after models were built, the rats were divided
into model group, large, middle, small dosage ~~group~~groups, negative
control group and positive control group which was administered with
Glucosidorum Tripterygll Totorum. The rats were ~~drenched~~given the

1 medicines orally once a day, lasting 5 days, ~~1 hours~~. One (1) hour after
2 administration for the last time, ~~and~~ 3ml of blood was taken from
3 abdominal aorta of rats and placed into test tube with 1% heparin as
4 ~~decoagulant, in which~~ an anticoagulant, and the whole blood viscosity
5 was measured at shear ~~rate~~rates of 230, 115, 46, 23, 11.5, 5.75S⁻¹ with an
6 NXE-1 cone and plate viscometer. The plasma viscosity was measured
7 with a WTP-BII adjustable constant pressure capillary viscosimeter. The
8 haematocrit, erythrocyte aggregation index was measured with the
9 centrifugation method of packed cell volume. The rigidity index was
10 calculated from the above-mentioned data. All the results ~~showed~~are
11 shown in table 13.

Table 13 Effect on hemorheology of adjuvant arthritis model rats ($\bar{X} \pm S$)

Groups	Control group	Model group	Fengshiping (30g/kg)	Fengshiping (15g/kg)	Fengshiping (7.5g/kg)	Glucosidorum Tripterygl Totorum (6mg/kg)
whole blood viscosity (mPa.s)						
230S-1	4.43±0.09	4.92±0.15**	4.56±0.09##	4.49±0.11##	4.54±0.16##	4.66±0.28#
115S-1	5.17±0.25	5.81±0.19**	5.33±0.09##	5.32±0.10##	5.16±0.14##	5.60±0.48#
46S-1	6.84±0.11	7.20±0.18**	6.56±0.13##	6.59±0.09##	6.67±0.14##	6.70±0.48#
23S-1	8.10±0.15	8.23±0.38	7.95±0.22	7.93±0.12	7.97±0.14	8.02±0.14
11.5S-1	9.35±0.08	9.78±0.10**	9.40±0.08##	9.45±0.10##	9.30±0.133	9.31±0.12##
6.5S-1	11.03±0.14	12.66±0.31**	11.21±0.21##	11.29±0.19##	11.60±0.40##	11.42±0.52##
Plasma (mPa.s)	1.158±0.032	1.248±0.040**	1.161±0.011##	1.154±0.023##	1.156±0.018##	1.158±0.029##
corpuscular volume (%)	46.13±2.31	41.33±1.12**	45.10±2.39##	44.33±1.52##	45.71±1.04##	46.03±3.59##
erythrocyte aggregation index	2.49±0.032	2.58±0.083*	2.46±0.066#	2.49±0.094#	2.44±0.048##	2.45±0.091#
Rigidity index	6.155±0.536	7.127±0.557**	6.506±0.558	6.525±0.146	6.394±0.200#	6.621±0.883

2 Compared with negative control group*P<0.05 , **P<0.01 ; compared with model control group# P<0.05 , ##
3 P<0.01

According to the table 13, the hemorheology of AA rats ~~were~~was changed significantly compared with control rats. The whole blood and plasma viscosity increased, haematocrit decreased, aggregation index and ~~rigity~~rigidity index of erythrocyte increased. ~~The~~ Fengshiping could ~~makes~~significantly improve the above-mentioned indexes of hemorheology ~~improved significantly~~.

Pharmacological effects of Fengshiping have been ~~proved~~proven by the above-mentioned experiments. Many important pharmacological effects of Fengshiping had favorable dosage-effect ~~relation~~correlation, which implied the best therapeutic effectiveness might be obtained by adjusting the drug dosage at the clinical work level.

The clinical studies on Fengshiping were carried on in China, Japan and Austrilia. Theses studies were ~~operated~~done according to international criterion related disease classification ~~about~~regarding diagnosis, therapy and curative effect. ~~By using the Fengshiping capsules Sololy, its~~The effective rate for RA was around 94%, and its ~~remarkable~~notable effective rate was around 60%. It could improve the symptoms such as morning stiffness, swelling and pain and ~~so on and the other~~ related items. The results showed in ~~table~~tables 14 ~ 21.

Table 14 Compared effect of treatment group with control group

Groups	Cases	remission (clinic al recovery)	Notable effect	Effective	No effect	Notable effect rate (%)	Effective rate (%)
Treatment group	32	5	14	11	2	59.38	93.74
Control group	30	3	10	12	5	43.33	83.33

Table 15 Influence of IgG, IgA and IgM ($\bar{X} \pm S$)

Groups	cases	IgG		IgA		IgM	
		pre -	post -	pre -	post -	pre -	post -
Normal	32	12.45±1.48		2.37±1.00		1.58±0.59	
Treatment group	32	16.92±3.49	14.17±1.39**	3.65±1.03	2.39±1.18**	1.89±0.88	1.48±1.01
Control	30	17.03±4.12	15.14±2.21**	3.45±1.86	2.32±1.75**	2.03±0.95	1.76±1.28

Comparing with pre-treatment **P<0.01

Table 16 Influence of C3 and C4($\bar{X} \pm S$)

groups	cases	C3		C4	
		pre -	post -	pre -	post -
normal group	32	0.62±0.13		0.14±0.15	
Treatment group	32	1.88±0.72	1.25±0.66**	0.48±0.12	0.26±0.06*
Control group	30	2.13±0.64	1.56±0.62**	0.40±0.16	0.25±0.07**

Comparing with before therapy *P<0.05, **P<0.01

Table 17 Influence of ESR and CRP ($\bar{X} \pm S$)

Groups	cases	ESR		CRP	
		pre-	post-	pre-	post-
Normal	32	8.37±5.26		4.12±1.88	
Treatment	32	66.58±9.01	30.31±6.53**	13.35±6.67	8.86±3.34*
control	30	73.33±9.09	35.83±11.61**	14.21±6.29	9.04±3.15**

Comparing with pre-treatment *P<0.05, **P<0.01

Table 18 Compared with power of gripping pre- and post-treatment ($\bar{X} \pm S$)

groups	Treatment Group		Control Group	
	pre -	post -	pre -	post -
Gripping power of left hands (mmHg)	39.13±20.24(15)	80.47±34.61**(15)	24.00±17.63(21)	55.15±23.27**(21)
Right hands	35.85±22.46(15)	85.32±36.32**(15)	22.80±12.32(21)	58.17±20.59**(21)

Comparing with pre-treatment *P<0.05, **P<0.01

Table 19 Influence of arthrosis swelling and pain and morning stiffness time ($\bar{X} \pm S$)

Items	Treatment Group		Control Group	
	pre -	post -	pre -	post -
arthrosis swelling and pain	5.79±0.52	3.14±0.83*	5.56±2.15	3.92±0.26*
morning stiffness time (minute)	50.33±6.47	20.24±3.27**	48.75±8.34	27.50±3.78**

Comparing with pre-treatment *P<0.05, **P<0.01

Table 20 Influence of RF changing to negative

Groups	Cases	RF negative		
		Pre - treatment	Post - treatment	Rate of negative turnaround (%)
Treatment group	32	24	11	54.2
Control group	30	18	10	44.4

Not only ~~had~~ did it show significant effects, for the above items in tables 14-20, but ~~also~~ Fengshiping can ~~make~~ also decrease the levels of items such as SIL-2R, STNF, SIL-6R in plasma decrease, results showing as shown in the Table 21.

Table 21 inflence of main indes such as SIL - 2R, STNF and SIL - 6R ($\bar{X} \pm S$)

groups	Cases	SIL - 2R(u/ml)		STNF R1(ng/ml)		SIL - 6R(ng/ml)	
		pre -	post -	pre -	post -	pre -	post -
Normal	32	299±68 (n=32)		1.56±0.48 (n=24)		72.05±18.26 (n=22)	
Fengshiping	15	683±189	381±157**	2.87±0.66	1.75±0.54**	136.18±28.57	90.15±20.12**
Control	10	765±203	412±167**	2.63±0.72	2.38±0.39 (n=8)	148.21±30.31	99.02±26.70**

Comparing with pre-treatment **P<0.01

It was ~~proved that~~ proven in the above-mentioned results ~~on that the~~

invention ~~could~~can be realized ~~only~~by the ways as ~~following~~follows:

Practice example 1:

Example of use 1:

Epimedium brevicornum Maxim. 2222g

Tripterygium hypoglaucum (Levl.) Hutch. 2222g

Lycium barbarum L. 1111g

Cuscuta chinensis Lam. 1111g

~~Four herbs hereinbefore,~~ *Tripterygium hypoglaucum* (Levl.) Hutch. was cut into pieces, extracted for three times ~~after~~with 13, 10, 10-fold ~~added in~~volume water, each time lasting 1 hour; *Epimedium brevicornum* Maxim was cut into segments, extracted three times ~~after~~with 15, 10, 10-fold~~volume~~water ~~was added in~~, each ~~extraction~~time lasting 1 hour; *Lycium barbarum* L. was crushed ~~to raw material~~into coarse powder, and immersed in 20-fold~~volume~~water of 80°C for 1 hour; *Cuscuta chinensis* Lam. was crushed ~~to raw~~into coarse powder, immersed in 31-fold~~volume~~water of 80°C for 1 hour; ~~the~~decoction fluid or immersion fluid of four herbs were filtrated ~~repectively~~respectively, poured ~~aeross~~across ~~macropore~~into column ~~with~~polymeric adsorbent column, ~~resins having macropores, and~~eluted with 70% ethanol. When the color of ~~effluent~~eluent became deep significantly, eluent was ~~commenced to collect; when~~collected until the color of ~~effluent~~eluent became very weak, ~~at which time the~~elution collection ~~was ended.~~
~~Eluent~~The alcohol in the eluent of each herb was ~~recyeled to get ethanol~~reduced. Then the fluid without alcohol was concentrated, ~~and~~dried to get the ~~finally extractive drug~~final extract powder; officinal starch was blended with the four kinds of ~~drug~~extract powder to 200g, mixed ~~up~~uniformly and encapsuled into 1000 capsules. Each capsule

which was prepared with the invented method thereof, was composed of 0.2g ~~drugs~~extractive~~drug~~ extract and contained at least 2.0mg of ~~icariine~~icariin C₃₃H₄₀O₁₅. The regular dosage is: oral administration, three times every day, three capsules ~~every~~each time.

Practice example 2:

Example of use 2:

Tripterygium hypoglaucum (Levl.) Hutch.2000g

Epimedium brevicornum Maxim.2000g

~~Two herbs hereinbefore,~~ *Tripterygium hypoglaucum* (Levl.) Hutch. ~~were~~was cut into pieces, extracted three times ~~after 13, 10, 10-fold added~~ in with 13, 10, 10-volume water, each time lasting 1 hour; ~~Epimedium brevicornum Maxim.~~Epimedium brevicornum Maxim. was cut into segments, extracted three times ~~after 15, 10, 10-fold water was added in,~~ each extraction with 15, 10, 10-volume water, each time lasting 1 hour; decoction fluid of herbs were filtrated ~~repectively~~respectively, poured ~~across macropore~~into column with polymeric adsorbent ~~column~~resins with macropores, eluted with 70% ethanol, when the color of ~~effluent~~eluent became deep significantly, eluent was ~~commenced to~~ collect; ~~when the color of effluent became very weak, elution was over.~~ ~~Eluent of each herbs was reecyled to get ethanol, concentrated, dried, finally extractive drug powder was obtained~~collected until eluent became very weak, at which time the elution ended. The alcohol in the eluent of each herb was removed. Then the fluid without alcohol was concentrated, dried to get the final extract powder; officinal starch was blended with the ~~extractive~~extracted drug powder, and mixed ~~up~~ uniformly, loaded to 1000 capsules. Each capsule which was prepared with the inventive method thereof, is composed of 0.2g drugs extractive,

contains at least 2.0mg of ~~icariine~~icariin $C_{33}H_{40}O_{15}$. regular dosage is: oral administration, three times every day, three capsules ~~every time~~for each time.

Practice example 3:

Example of use 3:

Tripterygium hypoglaucum (Levl.) Hutch. 2000g

Epimedium brevicornum Maxim. 2000g

Lycium barbarum L. 1000g

Tripterygium hypoglaucum (Levl.) Hutch. ~~werewas~~ cut into pieces, extracted three times ~~after~~with 13, 10, 10-fold ~~added in~~times water, each time lasting 1 hour; *Epimedium brevicornum* Maxim. was cut into segments, extracted three times ~~after~~with 15, 10, 10-fold ~~water was added in,~~times water, each time lasting 1 hour; *Lycium barbarum* L. was crushed to ~~raw material~~coarse powder, and immersed in 20-fold~~times~~ water of 80°C for 1 hour; decoction fluid or immersion fluid of four herbs were filtrated ~~repectively~~respectively, poured across a macropore polymeric adsorbent column, eluted with 70% ~~ethanol~~alcohol, when the color of effluent became deep significantly, eluent was ~~commenced~~started to ~~colleete~~be collected; when the color of effluent became very weak, elution was over. ~~Eluent of each herbs was recyceled to get ethanol,~~The alcohol in the eluent of each herb was recovered. Then the fluid without alcohol was concentrated, dried, to get the finally extractive drug powder was obtainedextract powder; officinal starch was blended with the extractive drug powder, and mixed up uniformly, loaded to 1000 capsules. Each capsule which was prepared with the inventive method thereof, is composed of 0.2g drugs extractive, contains at least 2.0mg of icariine $C_{33}H_{40}O_{15}$. Regular dosage is: oral administration, three times every day, three capsules ~~every~~each time.

Practice example 4

Example of use 4:

Tripterygium hypoglaucum (Levl.) Hutch. 2000g

Epimedium brevicornum Maxim. 2000g

Cuscuta chinensis Lam. 1000g

Tripterygium hypoglaucum (Levl.) Hutch. ~~werewas~~ cut into pieces, extracted three times ~~after~~with 13, 10, 10-fold ~~added in~~volume water, each time lasting 1 hour; *Epimedium brevicornum* Maxim. was cut into segments, extracted three times ~~after~~ 15, 10, 10-fold ~~water was added in,~~ each extraction with 15, 10, 10-volume water, each time lasting 1 hour; *Cuscuta chinensis* Lam. was crushed to ~~raw~~coarse powder, immersed in 31-fold volume water of 80°C for 1 hour; decoction fluid or immersion fluid of the herbs were filtrated ~~repectively~~respectively, poured across a macropore polymeric adsorbent column, eluted with 70% ethanol, when the color of effluent became deep significantly, collection of eluent ~~was commenced to collect~~began; when the color of effluent became very weak, elution was over. ~~Eluent of each herbs was recycled to get ethanol, concentrated, dried, finally extractive drug powder was obtained~~The alcohol in the eluent of each herb was reduced. Then the fluid without alcohol was concentrated, and dried to obtain the final extract powder; officinal starch was blended with ~~extractive~~extract drug powder, and mixed ~~up~~uniformly, loaded to 1000 capsules. Each capsule which was prepared with the inventive method thereof, is composed of 0.2g ~~drugs~~ extractive drug extract, contains at least 2.0mg of ~~icariine~~icariin C₃₃H₄₀O₁₅. Regular dosage is: oral administration, three times every day, three capsules ~~every~~each time.

Practice example 5

Example of use 5:

Tripterygium hypoglaucum (Levl.) Hutch. 2000g

Cuscuta chinensis Lam. 1000g

Tripterygium hypoglaucum (Levl.) Hutch. ~~Were~~was cut into pieces, extracted three times ~~after~~with 13, 10, 10-fold ~~added in~~volume water, each time lasting 1 hour; *Cuscuta chinensis* Lam. was crushed to ~~raw~~coarse powder, immersed in 31-fold volume water of 80°C for 1 hour; decoction fluid or immersion fluid of the herbs were filtrated ~~repectively~~respectively, poured across the macropore polymeric adsorbent column, eluted with 70% ethanol, when the color of effluent became deep significantly, collection of the eluent ~~was commenced to collect~~began; when the color of effluent became very weak, elution was over. ~~Eluent of each herbs was recycled to get ethanol,~~The alcohol in the eluent of each herb was recovered. Then the fluid without alcohol was concentrated, dried, to obtain the final finally ~~extractive drug~~extract powder ~~was obtained~~; officinal starch was blended with extractive drug powder, and mixed up uniformly, and loaded to 1000 capsules. ~~Dose~~The dose of capsules administered every day, which was prepared with the inventive method thereof, was equivalent to ~~dose of~~ 30g/day of crude drugs.

Practice example 6:

Example of use 6:

Tripterygium hypoglaucum (Levl.) Hutch. 2000g

Lycium barbarum L. 1000g

Tripterygium hypoglaucum (Levl.) Hutch. ~~were~~was cut into pieces,

extracted three times ~~after~~with 13, 10, 10-fold ~~added in~~volume water , each time lasting 1 hour; *Lycium barbarum* L. was crushed to ~~raw material~~coarse powder, and immersed in 20-fold~~volume~~ water of 80°C for 1 hour; decoction fluid or immersion fluid of the herbs were filtrated ~~repectively~~respectively, poured across macropore polymeric adsorbent column, eluted with 70% ethanol, when the color of effluent became deep significantly, collection of the eluent was commenced to collect~~began~~; when the color of effluent became very weak, elution was over. ~~Eluent of each herbs was reeyeled to get ethanol, concentrated, dried, finally extractive drug powder was obtained~~The alcohol in the eluent of each herb was recovered. Then the fluid without alcohol was concentrated, dried to obtain the final extract powder; officinal starch was blended with extractive drug powder, and mixed up uniformly, and loaded to 1000 capsules. ~~Dose~~The dose of capsules administered every day, which was prepared with the inventive method thereof, was equivalent to ~~dose of~~30g/day of crude drugs.

Claims

~~1. A pharmaceutical composition for treating rheumatism, characterized in that, it is made from the following materials:~~

~~Tripterygium hypoglaucum (Levl.) Hutch.~~

~~Epimedium brevicornum Maxim.~~

~~Lycium barbarum L.~~

~~Cuscuta chinensis Lam., Cuscuta australis R. Br.~~

~~Wherein the materials must be composed of Tripterygium hypoglaucum (Levl.) Hutch and one or two or three other herbs in the rest 3 herbs.~~

~~2. The pharmaceutical composition according to claim 1 made from the following materials:~~

~~Tripterygium hypoglaucum (Levl.) Hutch. 1-4 part by weight~~

~~Epimedium brevicornum Maxim. 1-4 part by weight~~

~~Lycium barbarum L. 1-4 part by weight~~

~~Cuscuta chinensis Lam., Cuscuta australis R. Br. 1-4 part by weight.~~

~~—3. The pharmaceutical composition according to claim 1 made from the following materials:~~

~~Tripterygium hypoglaucum (Levl.) Hutch. 2 part by weight~~

~~Epimedium brevicornum Maxim. 2 part by weight~~

~~Lycium barbarum L. 1 part by weight~~

~~Cuscuta chinensis Lam., Cuscuta australis R. Br. 1 part by weight~~

~~4. The pharmaceutical composition according to claim 1, characterized in that, it can be made from the correspond effective constituents of the~~

~~materials above mentioned as following that Epimedium brevicornum Maxim. can be replaced by any one or more than one among icariine, deuteroneicariine I, deuteroneicariine II and glyceicariine A; Tripterygium hypoglaucum (Levl.) Hutch can be replaced by diterpenoids, triterpenoids and alkaloids compound thereof, and Lycium barbarum L. and Cuscuta chinensis Lam. can be replaced by flavone contained thereof.~~

~~5. A method of preparing the pharmaceutical composition according to claim 1, 2 or 3, characterized in that, it includes the processes under-mentioned:~~

~~The raw herbs are weighed, and Epimedium brevicornum Maxim. and Tripterygium hypoglaucum (Levl.) Hutch. were cut into pieces respectively; including raw material or crushed powder of Lycium barbarum L. and Cuscuta chinensis Lam., four herbs hereinbefore, were extracted with 0-95% ethanol at 10-98°C respectively or combinatively for continuing 1-4 times. Ethanol was recycled respectively or combinatively in extracted fluid, then extraction was concentrated, dried, crushed, mixed uniformly or proportionally, manufactured to dosage form adopted in clinical work;~~

~~—Raw herbs were weighed: Epimedium brevicornum Maxim. and Tripterygium hypoglaucum (Levl.) Hutch. were cut into pieces, boiled out in water for three times respectively, and Lycium barbarum L. or Cuscuta chinensis Lam. were immersed in water of 80°C-95°C for 1-3 times respectively. Decoction or immersion fluids of three times of each herb were blended respectively, then mixture fluid was respectively poured through corresponding macropore polymeric adsorbent column. After absorption, resin column was washed with water until effluent became clear, then was eluted with 30-99.5% ethanol until color of~~

~~effluent became deep. Then eluent was collected until color of eluent became from deep to very weak while ethanol liquid was forced out from the column with water. Eluent was mixed with the ethanol liquid. The weight of total eluent was 1-8 fold of the herbs; eluent of each herbs was recycled, concentrated to specific gravity of 1.10 respectively, then extractive of every herbs were obtained by respective or combinative spray drying, which were mixed uniformly and proportionally, manufactured to dosage form adopted in clinical work.~~

~~6. A method of preparing the pharmaceutical composition according to claim 1, 2 or 3, characterized in that, it can be made into any dose forms adopted in the clinical work such as hard gelatin capsule, soft capsule, tablet, granule and injection.~~

~~—7. A method of preparing the pharmaceutical composition according to claim 1, 2 or 3, characterized in that, it includes the processes under-mentioned:~~

~~Tripterygium hypoglaucum (Levl.) Hutch. were cut into pieces, extracted three times after 13, 10, 10-fold added in respectively, each time lasting 1 hour; Epimedium brevicornum Maxim. was cut into segments, extracted three times after 15, 10, 10-fold water was added in respectively, each extraction lasting 1 hour; Lycium barbarum L. was crushed to raw material, and immersed in 20-fold water of 80°C-95°C for 1 hour; Cuscuta chinensis Lam. was crushed to raw powder, immersed in 31-fold water of 90°C for 1 hour; decoction fluid or immersion fluid of four herbs were filtrated respectively, poured through WLD or D₁₀₁ or other type of macropore polymeric adsorbent column, eluted with 70% ethanol, when the color of effluent became deep significantly, eluent was commenced to collect; when the color of effluent became very weak, elution was over. Eluent of each herbs was~~

~~recycled to get ethanol, concentrated, dried, finally extractive drug powder was obtained; which were mixed uniformly and proportionally, manufactured to dosage form adopted in clinical work.~~

~~8. The use of the pharmaceutical composition according to claim 1, 2 or 3 in the manufacture of a medicament for treating the rheumatoid and rheumatoid arthritis.~~

~~—9. The use of the pharmaceutical composition according to claim 1, 2 or 3 in the manufacture of a medicament for treating the systemic lupus erythematosus.~~

~~—10. The use of the pharmaceutical composition according to claim 1, 2 or 3 in the manufacture of a medicament for treating the chronic nephritis, crohn's disease and lepra reaction and the other autoimmune disease.~~

Abstract

~~The invention has brought to light a kind of antirheumatic and its preparation, which was made from Tripterygium hypoglaucum (Levl.) Hutch, Epimedium brevicornum Maxim, Lycium barbarum L, and Cuscuta chinensis Lam. The invented medicine has the merits of prominent effect, mild side reaction and convenient administration.~~

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